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Part III

Department of Health, Education, and Welfare

Food and Drug Administration

Medical Devices; Classification of Anesthesiology Devices

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 868

[Docket No. 78N-1648]

Classification of Anesthesiology Devices; Development of General Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing general rules applicable to the classification of all anesthesiology devices. The Medical Device Amendments of 1976 require FDA to classify all medical devices intended for human use into three categories: class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble to this proposal, FDA describes the development of the proposed regulations classifying individual anesthesiology devices, which are being published elsewhere in this issue of the **Federal Register**. The preamble also describes the activities of the Anesthesiology Device Classification Panel, an FDA advisory committee that makes recommendations to FDA concerning the classification of anesthesiology devices.

DATES: Comments on or before January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-0305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Device Classification System

The Medical Device Amendments of 1976 (Pub. L. 94-295), hereinafter called the amendments, establish a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: class I, general controls; class II, performance standards; and class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the Panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is also classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. The two types of devices just noted are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

Related Regulations

In the **Federal Register** of July 28, 1978 (43 FR 32988), FDA issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the **Federal Register** of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the **Federal Register** of May 19, 1975 (40 FR 21848).

Activities of Panel

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Anesthesiology Device Classification Panel (the Panel) was originally chartered on October 3, 1972, as the Panel on Review of Anesthesiology Devices.

On August 9, 1976, the Panel and other preamendments device classification panels were rechartered to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panel reviewed all devices referred to it by FDA to make certain that its recommendations were in accord with the amendments.

Throughout the Panel's deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of anesthesiology devices. The Panel also invited experts to testify and sought information on many devices from the published literature.

In November 1977, the Panel submitted to FDA a preliminary report of its recommendations. The report included a roster of current and previous Panel members and consultants and listed all meeting dates. The agency placed a copy of the report in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, and announced its availability to the public by notice published in the **Federal Register** of November 29, 1977 (42 FR 60792). At a meeting held on January 24, 1978, the Panel changed its previous recommendations concerning the classification of several devices. An addendum to the Panel report showing these changes has been placed in the office of the Hearing Clerk, Food and Drug Administration. Also available in the office of the Hearing Clerk are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual anesthesiology device proposed classification regulations. Interested persons may review these documents in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

List of Anesthesiology Devices

In 1972, FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of anesthesiology devices. The Panel supplemented the list using its members' knowledge of anesthesiology devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not included.

FDA is proposing to establish a new Part 868 in Title 21 of the Code of

Federal Regulations. Part 868 will consist of sections identifying each anesthesiology device with a brief narrative description and stating the classification of that device. A list of the anethesiology devices appears elsewhere in this preamble.

Individual Anesthesiology Device Classification Regulations

Elsewhere in this issue of the **Federal Register**, FDA is issuing 149 individual proposed regulations to classify each anesthesiology device. The agency is proposing to classify 22 anesthesiology devices into class I (general controls), 119 anesthesiology devices into class II (performance standards), and 8 anesthesiology devices into class III (premarket approval). The agency also is publishing the recommendations of the Panel regarding these devices, as required by section 513(c)(2) and (d)(1) of the act (21 U.S.C. 360c(c)(2) and (d)(1)).

Published Panel Recommendations

Each published Panel recommendation concerning an anesthesiology device includes the information described below.

1. *Identification.* The Panel recommendation and proposed FDA classification regulation each include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 868.1, any manufacturer of a newly offered device who files a premarket notification submission under section 510(k) of the act and Part 807 of the regulations cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a new device may be described accurately be the title and identification in a classification regulation, it is nevertheless in a class III under section 513(f) of the act if it is not substantially equivalent to a preamendment device (or to a postamendment device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to devices previously classified by the regulation. FDA believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why it believes the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I, class II, class III.

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). Although the Panel did not recommend that any device be exempted at this time from section 510 or section 519 of the act, the Panel did recommend that the manufacturers of several class I devices be exempted from the good manufacturing practice regulation in the manufacture of these devices. The agency's policy concerning these exemption recommendations is discussed below in the section of this proposal concerning "Exemptions for Class I Devices."

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "medium," or "low") for establishing a performance standard for the device. Similarly, each Panel recommendation that a device be classified into class III includes the Panel's recommended priority ("high," "medium," or "low") for application of premarket approval requirements to that device. As explained below in the section of this notice concerning "Priorities for Class II and III Devices," FDA is not, however, proposing the establishment of agency priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes a particular device meets the statutory criteria for classification into class I, II, or III.

Except in those instances in which FDA's classification proposal differs form the Panel's recommendation, FDA is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

The summary of reasons for a recommendation identifies any device that is an implant or a life-supporting or life-sustaining device. The summary of reasons for any implant or life-supporting or life-sustaining device that is not recommended for classification into class III also explains why the Panel determined that classification of the device into class III is unnecessary to provide reasonable assurance of its safety and effectiveness. The agency provides a similar explanation in the "Proposed Classification" section of the preamble to any proposal to classify an implant or a life-supporting or life-sustaining device into a class other than class III.

4. *Summary of data on which the recommendation is based.* In many cases, the Panel based its recommendations on Panel members' personal knowledge of, and clinical experience with, the devices under review. Reliance on the Panel members' clinical experience and judgment was particularly common when the Panel considered a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments states that the term "data" has a special meaning in section 513(c)(2)(A) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in this section, "data" refers not only to the results of scientific experiments but also to less formal evidence, other scientific information, or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H. Rept. 94–853, 94th Congress, 2d Session (1976)). FDA has determined that clinical experience and judgment are valid scientific evidence for classifying certain devices.

In many cases, FDA sought data and information concerning the classification of a device in addition to that cited by the Panel. References to these data and information are found in the "Proposed Classification" section of the preambles to individual anesthesiology device regulations. FDA is adopting, as the agency's statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulations.

5. *Risks to health.* In identifying the risks to health presented by anesthesiology devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to the use of a device. In some cases, FDA has

identified additional risks to health presented by a device. These additional risks are set out in the section of the preamble concerning the "Proposed Classification" of a particular device.

Because the classification recommendations and FDA regulations do not identify all risks to health presented by anesthesiology devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) and future regulations requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed Classification

Each proposed regulation to classify an anesthesiology device states whether FDA agrees with the Panel's recommendation, describes the agency's proposed classification of the device, and proposes a new section in Part 868 in which the device classification will be condified.

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments received in response to the proposal, new data and information, and the agency's reconsideration of existing information.

Priorities for Class II and Class III Devices

For a device that the Panel recommends be classified into class II or class III, section 513(c)(2)(A) of the Act requires that the Panel recommendation include, to the extent practicable, a recommendation for the assignment of a priority for application to the device of performance standards or premarket approval requirements. In reaching its determination on priorities, the Panel compared the relative risks and benefits of the particular device with those of other anesthesiology devices. The Panel recommended a "high priority" assignment only to those devices it believed warranted the agency's immediate attention.

FDA is not proposing at this time the establishment of priorities either for development of performance standards for class II devices or for application of premarket approval requirements to class III devices, section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. The agency, however, will establish such priorities in the future. These priorities will be based on the classification panels' recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the **Federal Register.**

To the extent it is not constrained by statute or available resources, the agency intends to impose premarket approval requirements on class III devices as soon as possible.

FDA's action of requiring submission of premaket approval applications for particular class III devices is dependent upon the number of devices reviewed by a panel and the priority of a particular device in relation to other class III devices considered by a panel. For example, when FDA classifies only a few devices within a panel's specialty area as class III, FDA may simultaneously publish regulations under section 515(b) requiring premarket approval for many class III devices considered by the Panel, regardless of whether a high or low priority has been established for the devices. Where practical, FDA will publish these regulations during the post classification grace period (at least 30 months) when a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is provided for in section 501(f) of the act (21 U.S.C. 351(f)).

Exemptions for Class I Devices

Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) provides that FDA may exempt a device recommended for classification into class I from a requirement under the following sections of the act: section 510 (21 U.S.C. 360), registration; section 519 (21 U.S.C. 360i), records and reports; and section 520(f) (21 U.S.C. 360j(f)), good manufacturing practices.

Under section 510 of the act, a person "engaged in the manufacture, preparation, propagation, compounding or processing of * * * a device or devices" must register with FDA (section 510 (b) through (i)), file a list of devices (section 510(j)), and notify FDA at least 90 days before beginning commercial distribution of a device (section 510(k)). (See Part 807 (21 CFR Part 807).) Section 510(g)(4) authorizes the agency to exempt a device from section 510 if it finds that compliance with that section is not necessary for the protection of the public health. In § 807.65 (21 CFR 807.65), FDA has exempted certain classes of persons from section 510 of the act. Several device classification panels have recommended that manufacturers of certain class I devices also be exempted from all or some of the requirements of section 510. The agency has determined that protection of the public health requires that manufacturers of medical devices, other than those already exempt under § 807.65, register and list their products with FDA to ensure that the agency can identify these manufacturers and their products and conduct necessary inspections.

The agency has determined, however, for certain devices, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions. Thus, the agency is proposing to exempt certain devices from Subpart E of Part 807 of the regulations, which implements section 510(k) of the act. The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice of new products within these generic types of devices.

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to establish and maintain such records, make such reports, and provide such information as the agency may reasonably require to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation under Part 820 (21 CFR Part 820), published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations in accordance with section 519 of the act, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempted from the requirements, and FDA will issue exemptions that are appropriate.

The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from most requirements of the device GMP regulation. As explained below,

the exemption will not extend to two device GMP records requirements.

The device GMP regulation was published in final form in the **Federal Register** of July 21, 1978. At the time of the Panel's recommendations, the GMP regulations had not yet been promulgated, and the agency had not yet developed criteria for exempting a class I device from GMP requirements. The agency has now decided that, if any one of the following criteria is met, FDA will consider exempting from the GMP regulation a class I device that is not labeled or otherwise represented as sterile. The agency will not, however, exempt a device from § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, or § 820.198 (21 CFR 820.198), with respect to complaint files. The criteria are:

1. FDA has determined, based on adequate information about current practices in the manufacture of the device and about user experience with the device, that application of GMP regulation is unlikely to improve the safety and effectiveness of the device.

2. FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or routine testing before use, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. FDA has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device GMP regulation. Such a device must be subject to the entire GMP regulation to ensure that manufacturers adequately reduce the bioburden (number of microorganisms) on the device and its components during the manufacturing process. This reduction is accomplished through adherence to a comprehensive quality assurance program as is required by the GMP regulation, with adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging and labeling controls, and other quality assurance measures.

The agency also has determined that no exemption from the device GMP regulation will extend to § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufactures. To ensure that device manufacturers have adequate systems for complaint investigation and followup, all such manufacturers are required to comply with the complaint file requirements of § 820.198. All device manufacturers also are required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

In general, FDA has not initiated proposals to exempt manufacturers of class I devices from requirements under section 510, 519, or 520(f) but has acted on the basis of exemption recommendations of the device classification panels. Manufacturers and other interested persons may submit comments on the appropriateness of exemptions of manufacturers of class I devices that are not the subject of panel exemption recommendations. FDA will consider granting exemptions from the requirement of premarket notification and from the GMP regulation (other than §§ 820.180 and 820.198) according to the policies and criteria discussed above. Comments requesting additional exemptions should be supported by information showing that the exemption of manufacturers of a device from the premarket notification requirement or the GMP regulation (other than §§ 820.180 and 820.198), or both, is consistent with the policies and criteria discussed above.

List of Anesthesiology Devices

The following is a list of anesthesiology devices that FDA is proposing to classify, the Code of Federal Regulations section under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Section and device	Docket No.	Class
Subpart B—Diagnostic Devices		
868.1030 Manual algesimeter	78N-1649	I
868.1040 Powered algesimeter	78N-1650	II
868.1075 Argon gas analyzer	78N-1651	II
868.1100 Arterial blood sampling kit	78N-1652	II
868.1110 Nonindwelling blood carbon monoxide analyzer	78N-1653	II
868.1120 Indwelling blood oxyhemoglobin concentration analyzer	78N-1654	III
868.1130 Nonindwelling blood oxyhemoglobin concentration analyzer	78N-1655	II
868.1150 Indwelling blood carbon dioxide partial pressure (P_{CO}) analyzer	78N-1657	III
868.1160 Nonindwelling blood carbon dioxide partial pressure (P_{CO}) analyzer	78N-1658	II
868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer	78N-1659	III
868.1180 Nonindwelling blood hydrogen ion concentration (pH) analyzer	78N-1660	II
868.1190 Nonindwelling blood nitrogen partial pressure (PN_2) analyzer	78N-1661	II
868.1200 Indwelling blood oxygen partial pressure (P_O) analyzer	78N-1662	III
868.1210 Nonindwelling blood oxygen partial pressure (P_O) analyzer	78N-1663	II
868.1250 Calibrated breathing system collection bottle	78N-1664	II
868.1260 Uncalibrated breathing system collection bottle	78N-1665	I
868.1400 Carbon dioxide gas analyzer	78N-1666	II
868.1430 Carbon monoxide gas analyzer	78N-1667	II
868.1500 Enflurane gas analyzer	78N-1668	II
868.1575 Gas collection vessel	78N-1669	II
868.1620 Halothane gas analyzer	78N-1670	II
868.1640 Helium gas analyzer	78N-1671	II
868.1670 Neon gas analyzer	78N-1672	II
868.1690 Nitrogen gas analyzer	78N-1673	II
868.1700 Nitrous oxide gas analyzer	78N-1674	II
868.1720 Oxygen gas analyzer	78N-1675	II
868.1730 Oxygen uptake computer	78N-1676	II
868.1750 Pressure plethysmograph	78N-1677	II
868.1760 Volume plethysmograph	78N-1678	II
868.1780 Inspiratory airway pressure meter	78N-1679	II
868.1800 Rhinoanemometer	78N-1680	II
868.1840 Diagnostic spirometer	78N-1681	II
868.1850 Monitoring spirometer	78N-1682	II
868.1860 Peak-flow meter for spirometry	78N-1683	II
868.1870 Gas volume calibrator	78N-1684	II
868.1880 Pulmonary-function data calculator	78N-1685	II
868.1890 Predictive pulmonary-function value calculator	78N-1686	II
868.1900 Diagnostic pulmonary-function interpretation calculator	78N-1687	II
868.1910 Esophageal stethoscope	78N-1688	I
868.1920 Esophageal stethoscope with electrical conductors	78N-1689	II
868.1930 Stethoscope head	78N-1690	I
868.1965 Switching valve (ploss)	78N-1691	I
868.1975 Water vapor analyzer	78N-1692	II
Subpart C—Monitoring Devices		
868.2025 Ultrasonic air embolism monitor	78N-1693	II
868.2300 Bourdon gauge flowmeter	78N-1694	II
868.2320 Uncompensated thrope tube flowmeter	78N-1695	II
868.2340 Compensated thrope tube flowmeter	78N-1696	II
868.2350 Gas calibration flowmeter	78N-1697	II
868.2375 Breathing frequency monitor	78N-1698	II
868.2450 Lung water monitor	78N-1699	III
868.2500 Cutaneous oxygen monitor	78N-1700	II
868.2550 Pneumotachometer	78N-1702	II
868.2600 Airway pressure monitor	78N-1703	II
868.2610 Gas pressure gauge	78N-1704	II
868.2620 Gas pressure calibrator	78N-1705	II
868.2700 Pressure regulator	78N-1706	II
868.2775 Electrical peripheral nerve stimulator	78N-1707	II
868.2875 Differential pressure transducer	78N-1708	II
868.2885 Gas flow transducer	78N-1709	II

Section and device	Docket No.	Class
868.2900 Gas pressure transducer	78N-1710	II
Subpart F—Therapeutic Devices		
868.5090 Emergency airway needle	78N-1714	II
868.5100 Nasopharyngeal airway	78N-1715	II
868.5110 Oropharyngeal airway	78N-1716	II
868.5120 Anesthesia conduction catheter	78N-1717	II
868.5130 Anesthesia conduction filter	78N-1718	II
868.5140 Anesthesia conduction kit	78N-1719	II
868.5150 Anesthesia conduction needle	78N-1720	II
868.5160 Anesthesia gas machine	78N-1721	II
868.5170 Laryngotracheal topical anesthesia applicator	78N-1722	II
868.5180 Rocking bed	78N-1723	II
868.5220 Blow bottle	78N-1726	I
868.5240 Anethesia Breathing circuit	78N-1727	II
868.5250 Breathing circuit circulator	78N-1728	II
868.5260 Breathing circuit bacterial filter	78N-1729	II
868.5270 Breathing system heater	78N-1730	II
868.5280 Breathing tube support	78N-1731	I
868.5300 Carbon dioxide absorbent	78N-1732	II
868.5310 Carbon dioxide absorber	78N-1733	II
868.5320 Reservoir bag	78N-1734	II
868.5330 Breathing gas mixer	78N-1735	II
868.5340 Nasal oxygen cannula	78N-1736	I
868.5350 Nasal oxygen catheter	78N-1737	I
868.5365 Posture chair for cardiac and pulmonary treatment	78N-1738	I
868.5375 Heat and moisture condenser (artificial nose)	78N-1739	II
868.5385 Water-seal thoracic drainage system	78N-1740	II
868.5400 Electroanesthesia apparatus	78N-1741	III
868.5420 Ether hook	78N-1743	I
868.5430 Gas-scavenging apparatus	78N-1744	II
868.5440 Portable oxygen generator	78N-1745	II
868.5450 Respiratory gas humidifier	78N-1746	II
868.5460 Humidifier for home use	78N-1747	II
868.5470 Hyperbaric chamber	78N-1748	II
868.5480 Hyperthermia device	78N-1749	II
868.5490 Hypothermia device	78N-1750	II
868.5520 Automatic catheter flushing device	78N-1751	II
868.5530 Flexible laryngoscope	78N-1752	II
868.5540 Rigid laryngoscope	78N-1753	II
868.5550 Anesthetic gas mask	78N-1754	II
868.5560 Gas mask head strap	78N-1755	I
868.5570 Nonrebreathing mask	78N-1756	II
868.5580 Oxygen mask	78N-1757	I
868.5590 Scavenging mask	78N-1758	II
868.5600 Venturi mask	78N-1759	II
868.5610 Membrane lung for long-term pulmonary support	78N-1760	III
868.5620 Breathing mouthpiece	78N-1761	II
868.5630 Nebulizer	78N-1762	II
868.5640 Medicinal nonventilatory nebulizer (atomizer)	78N-1763	I
868.5650 Esophageal obturator	78N-1764	II
868.5655 Portable liquid oxygen unit	78N-1765	II
868.5665 Electric-powered percussor	78N-1766	II
868.5675 Rebreathing device	78N-1767	I
868.5690 Incentive spirometer	78N-1768	II
868.5700 Oxygen tent	78N-1769	I
868.5710 Electrically powered oxygen tent	78N-1770	II
868.5720 Bronchial tube	78N-1771	II
868.5730 Tracheal tube	78N-1772	II
868.5740 Tracheal/bronchial differential ventilation tube	78N-1773	II
868.5750 Inflatable tracheal tube cuff	78N-1774	II
868.5760 Cuff spreader	78N-1775	I
868.5770 Tracheal tube fixation device	78N-1776	II
868.5780 Tube introduction forceps	78N-1777	II
868.5790 Tracheal tube stylet	78N-1778	II
868.5810 Airway connector	78N-1780	II
868.5820 Dental protector	78N-1781	II
868.5830 Autotransfusion apparatus	78N-1782	III
868.5840 Blood transfusion microfilter	78N-1783	II
868.5860 Pressure tubing and accessories	78N-1784	II
868.5870 Nonrebreathing valve	78N-1785	II
868.5880 Anesthetic vaporizer	78N-1786	II
868.5895 Continuous ventilator	78N-1787	II
868.5905 Noncontinuous ventilator	78N-1788	II
868.5915 Manual emergency ventilator	78N-1789	II
868.5925 Powered emergency ventilator	78N-1790	II
868.5935 External negative pressure ventilator	78N-1791	II
868.5955 Intermittent mandatory ventilation attachment	78N-1793	II
868.5965 Positive end expiratory pressure breathing attachment	78N-1794	II
868.5975 Ventilator tubing	78N-1795	II
868.5995 Tee drain (water trap)	78N-1796	II
Subpart G—Miscellaneous Devices		
868.6100 Anesthetic cabinets, tables or trays	78N-1797	I
868.6175 Cardiopulmonary emergency cart	78N-1798	I
868.6225 Nose clip	78N-1799	I
868.6250 Portable air compressor	78N-1800	II
868.6275 Gas cylinder	78N-1801	II
868.6285 Gas cylinder holder	78N-1802	II
868.6400 Calibration gas	78N-1805	II
868.6700 Anethesia stool	78N-1806	I
868.6810 Tracheobronchial suction catheter	78N-1810	I
868.6820 Patient position support	78N-1807	II
868.6985 Medical gas yoke assembly	78N-1808	II

Devices Considered by Two or More Panels

Many devices were reviewed by two or more device classification panels. For these devices, FDA will publish each panel's recommendations and a single proposed classification regulation. The following devices were considered by the Anesthesiology Device Classification Panel and by other panels:

1. The General and Plastic Surgery Device Classification Panel recommend that continuous oxygen analyzers be classified into class III. The General Hospital and Personal Use Device Classification Panel recommended that neonatal invasive oxygen analyzers be classified into class III. The Anesthesiology Device Classification Panel recommended that indwelling blood oxygen partial pressure (P_{o_2}) analyzers be classified into class III. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the indwelling blood oxygen partial pressure (P_{o_2} analyzer into class III, and is publishing the Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

2. The Dental Device Classification Panel recommended that anesthesia flowmeters be classified into class II. The Anesthesiology Device Classification Panel recommended that back-pressure compensated thorpe tube flowmeters be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying compensated thorpe tube flowmeters into class II, and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

3. The General Hospital and Personal Use Device Classification Panel recommended that the manual pulmonary resusitator be classified into class II. The Anesthesiology Device Classification Panel recommended that the manual emergency ventilator be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the manual emergency ventilator into class II, and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

4. The General Hospital and Personal Use Device Classification Panel recommended that the neonatal ventilator be classified into class II. The Anesthesiology Device Classification Panel recommended that the continuous ventilator be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying the continuous ventilator into class II and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

(5) The General Hospital and Personal Use Device Classification Panel recommends that nasal cannulas be classified into class I. The Anesthesiology Device Classification Panel recommends that nasal oxygen cannulas be classified into class I. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying nasal oxygen cannulas into class I and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

6. The Dental Device Classification Panel recommends that gas machine analgesia/anesthesia be classified into class II. The Anesthesiology Device Classification Panel recommends that anesthesia gas machines be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying anesthesia gas machines into class II and is publishing both Panels' recommendations in a

proposal appearing elsewhere in this issue of the **Federal Register.**

7. The Dental Device Classification Panel recommends that compressed gas cylinders and valves be classified into class II. The Anesthesiology Device Classification Panel recommends that gas cylinders be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying gas cylinders into class II and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

8. The General Hospital and Personal Use Device Classification Panel recommends that oxygen masks be classified into class II. The Anesthesiology Device Classification Panel recommends that oxygen masks be classified into class II. The FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying oxygen masks into class II and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

9. The General Hospital and Personal Use Device Classification Panel recommends that venturi oxygen masks be classified into class II. The Anesthesiology Device Classification Panel recommends that venturi masks be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying venturi masks into class II and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

10. The General and Plastic Surgery Device Classificaiton Panel recommends that respiratory monitors be classified into class II. The Anesthesiology Device Classification Panel recommends that ventilatory frequency monitors be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying ventilatory frequency monitors into class II and is publishing both Panel recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

11. The General Hospital and Personal Use Device Classification Panel recommends that mechanical oxygen regulators be classified into class II. The Anesthesiology Device Classification Panel recommends that pressure regulators be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying pressure regulators into class II and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

12. The Dental Device Classification Panel recommends that emergency oxygen and resuscitation units be classified into class II. The Anesthesiology Device Classification Panel recommends that powered emergency ventilators be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying powered emergency ventilators into class II and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

13. The Neurological Device Classification Panel recommends that electroanaesthesia stimulators be classified into class III. The Anesthesiology Device Classification Panel recommends that electroanesthesia apparatus be classified into class III. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying electroanesthesia apparatus into class III and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

14. The General Hospital and Personal Use Device Classification Panel recommends that pediatric aerosol tents be classified into class II. The Anesthesiology Device Classification Panel recommends that electrically powered oxygen tents be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying electrically powered oxygen tents into class II and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.**

15. The Cardiovascular Device Classification Panel recommends that pH catheter probes be classified into class II (**Federal Register** of March 9, 1979, 44 FR 13303). The Anesthesiology Device Classification Panel recommends that the indwelling blood hydrogen ion concentration (pH) analyzer be classified into class III. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying indwelling blood hydrogen ion concentration analyzer into class III and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the **Federal Register.** The pH catheter probe will be deleted from the published final orders of the Cardiovascular Device Classification Panel.

16. The Anesthesiology Device Classification Panel and the other panels listed below made classification recommendations concerning the following devices:

Device	Other panel(s)
Transcutaneous ultrasonic blood flowmeter.	Cardiovascular.
Indwelling blood flow transducer	Cardiovascular.
Blood pressure monitor amplifier and associated electronics.	Cardiovascular.
Indwelling blood pressure monitor	Cardiovascular.
Nonindwelling blood pressure monitor	Cardiovascular.
Indwelling blood pressure transducer	Cardiovascular.
Nonindwelling blood pressure transducer	Cardiovascular.
Electrocardiographic monitor	Cardiovascular.
Pulse rate monitor	Cardiovascular.
Mechanical cardiac resuscitator	Cardiovascular.
Rigid bronchoscope aspirating tube	Ear, nose, and throat.
Nonrigid bronchoscope	Ear, nose, and throat.
Rigid nonventilating bronchoscope	Ear, nose, and throat.
Rigid ventilating bronchoscope	Ear, nose, and throat.
Bronchoscope biopsy brush (nonrigid)	Ear, nose, and throat.
Bronchoscope foreign body claw (nonrigid)	Ear, nose, and throat.
Bronchoscope biopsy currette (nonrigid)	Ear, nose, and throat.
Bronchoscope biopsy currette (rigid)	Ear, nose, and throat.
Bronchoscope biopsy forceps (nonrigid)	Ear, nose, and throat.
Bronchoscope biopsy forceps (rigid)	Ear, nose, and throat.
Bronchoscope tubing	Ear, nose, and throat.
Tracheostomy tube	Ear, nose, and throat.
Arm board	General and plastic surgery.
Electrosurgical unit	General and plastic surgery.
Portable aspiration pump	General and plastic surgery.
Conductive patient restraint	General and plastic surgery.
Conductive shoe and shoe cover	General and plastic surgery.
Operating room table and attachments	General and plastic surgery.
Manual infusion apparatus	General hospital.
Powered infusion apparatus	General hospital.
Patient cart	General hospital.
Infusion rate monitor	General hospital.
Spinal-fluid pressure monitor	General hospital.
AC-powered spinal fluid pressure monitor	General hospital.
Nasogastric tube	General hospital.
Temperature monitor (self-contained)	General hospital.
Temperature monitor (w/probe)	General hospital.
Suction regulator	General hospital.
Transfusion set	General hospital.
Rigid suction tip	General hospital.
Sterile specimen trap	General hospital.
Flexible aspirating tube	General hospital.
Electrophrenic pacer	Neurology.
Bicycle ergometer	Physical medicine.
Treadmill	Physical medicine.
Grip strength dynamometer	Orthopedic.
Electromagnetic blood warmer	Hematology.
Nonelectromagnetic blood warmer	Hematology.

FDA is not at this time publishing the Anesthesiology Device Classification Panel's recommendations to classify the devices listed above. FDA will publish

these recommendations, and proposed classification regulations, when the agency publishes the recommendations of other panels that reviewed the devices. Some of these other Panels' recommendations have already been published in the **Federal Register** as noted below:

Neurology—November 28, 1978 (43 FR 54640–55732) (proposals). September 4, 1979 (44 FR 51726–51778) (final orders).
Cardiovascular—March 9, 1979 (44 FR 13284–13434) (proposals).
General Hospital—August 24, 1979 (44 FR 49844–49954) (proposals).
Physical Medicine—August 28, 1979 (44 FR 50458–50537) (proposals).
Hematology—September 11, 1979 (44 FR 52950–53063) (proposals).

FDA has determined that the following devices reviewed by the Anesthesiology Device Classification Panel are identical to devices reviewed by the Neurological Device Classification Panel and the Cardiovascular Device Classification Panel: electroencephalograph; surface electrodes; needle electrode; transcutaneous blood oxyhemoglobin concentration analyzer; and bit block. FDA has also determined that these anesthesiology devices should be regulated under the regulations proposed or adopted for the counterpart devices reviewed by the other two panels. FDA will not, therefore, issue proposed regulations based on the Anesthesiology Device Classification Panel's recommendations. Because, however, the proposed and final neurological device classification regulations, and the proposed cardiovascular device classification regulations, were published before FDA determined that the devices in question were identical, the agency did not publish the Anesthesiology Device Classification Panel's recommendations at that time. Accordingly, the agency is publishing, below, the recommendations of the Anesthesiology Device Classification Panel concerning these devices, as required by the amendments. Interested persons are invited to comment, in accordance with the procedure set forth at the end of this notice, on the agency's determinations that the devices described below are identical to the neurological or cardiovascular devices referred to.

1. The Anesthesiology Device Classification Panel recommends that the electroencephalograph be classified into class II because it believes that the electroencephalograph should accurately reproduce the electroencephalogram. The Panel based its recommendation on the Panel members' clinical experience with this device. The Panel identified electrical shock as a risk to health from use of this device.

FDA has determined that the electroencephalograph classified by the Anesthesiology Device Classification Panel is identical to the device considered by the Neurological Device Classification Panel. On November 28, 1978, FDA published in the **Federal Register** (43 FR 55653) a proposed regulation, based on that Panel's recommendation, classifying the electroencephalograph into class II.

2. The Anesthesiology Device Classification Panel recommends that a surface electrode be classified into class II because it believes the surface electrode should accurately reproduce physiologic signals and use only acceptable materials. The Panel based its recommendation on the Panel members' clinical experience with this device. The Panel identified electrical shock and biocompatability as risks to health associated with the use of this device.

The agency has determined that the surface electrode classified by the Anesthesiology Device Classification Panel is identical to the device considered by the Neurological Device Classification Panel. On November 28, 1978, FDA published in the **Federal Register** (43 FR 55650) a proposed regulation based on that Panel's recommendation, classifying the cutaneous electrode into class II.

3. The Anesthesiology Device Classification Panel recommends that the needle electrode be classified into class II because it believes that the needle electrode should accurately reproduce physiologic signals and use only acceptable materials. The Panel based its recommendation on the Panel members' clinical experience with this device. The Panel identified electrical shock and biocompatability as risks to health associated with the use of this device.

FDA has determined that the needle electrode classified by the Anesthesiology Device Classification Panel is identical to the device considered by the Neurological Device Classification Panel. On November 28, 1978, FDA published in the **Federal Register** (43 FR 55652) a proposed regulation, based on that Panel's recommendation, classifying the needle electrode into class II.

4. The Anesthesiology Device Classification Panel recommends that the transcutaneous blood oxyhemoglobin concentration analyzer be classified into class II because it believes that the design of the device should be controlled to assure accurate and reproducible blood oxyhemoglobin concentration values. The Panel based its recommendation on the Panel members' clinical experience with this device. The Panel identified local irritation or burns and erroneous data leading to inappropriate therapy as risks to health associated with this device.

FDA has determined that the transcutaneous blood oxyhemoglobin concentration analyzer classified by the Anesthesiology Device Classification Panel is identical to the device considered by the Cardiovascular Device Classification Panel. On March 9, 1979, FDA published in the **Federal Register** (44 FR 13346) a proposed regulation, based on that Panel's recommendation, classifying the ear oximeter into class II.

5. The Anesthesiology Device Classification Panel recommends that a bite block be classified into class II because it believes that a bite block should adequately protect the patient's teeth and use only acceptable materials. The Panel based its recommendation on the Panel members' clinical experience with this device. The Panel identified trauma and infection as risks to health associated with the use of this device.

FDA has determined that the bite block classified by the Anesthesiology Device Classification Panel is identical to the device considered by the Neurological Device Classification Panel. On November 28, 1978 FDA published in the **Federal Register** (43 FR 55652) a proposed regulation, based on that Panel's recommendation, classifying a bite block into class II.

Devices Reviewed by the Panel but for Which No Regulation Is Proposed

FDA is not issuing proposed regulations classifying the following devices reviewed by the Anesthesiology Device Classification Panel:

1. The Anesthesiology Device Classification Panel recommends that the ether dropper, a device used to administer ether anesthetic, be classified into class II because it believes that the device should accurately dispense the correct amount of ether.

FDA agrees with the Panel recommendation, but is unaware of any such product in commercial distribution. The agency requests the submission of any information regarding the commercial distribution of the ether dropper.

2. The Anesthesiology Device Classification Panel recommends that airway suction kits, a device in kit form used to remove secretions from the respiratory tract, be classified into class

II because it believes that the device should comply with a sterility standard.

The devices usually used for removing secretions from the respiratory tract (e.g., tracheobronchial suction catheter) are the subjects of individual proposed classification regulations published in this issue of the **Federal Register**. Accordingly, there is no need to publish a separate regulation for those devices when sold as a "kit."

3. The Anesthesiology Device Classification Panel recommended that both attached and unattached cigarette filters be classified into class III (premarket approval) because it believes that insufficient information exists to determine that general controls or standards would be adequate to provide reasonable assurance of the safety and effectiveness of these devices.

On October 2, 1978, Action on Smoking and Health (ASH) filed a petition requesting that FDA recognize its jurisdiction over cigarette filters and regulate them as medical devices. FDA is not now issuing a proposed classification regulation for cigarette filters pending a decision on the ASH petition and a determination of the regulatory status of cigarette filters.

4. The Anesthesiology Device Classification Panel recommends that acupuncture needles be classified into class II and that acupuncture point locators and electroacupuncture stimulators be classified into class III.

FDA is not publishing a proposed regulation to classify these devices because the devices have already been classified into class III by statute and such a proposal is therefore unnecessary.

FDA believes that these devices have not been shown to be safe and effective for any therapeutic or diagnostic use. In recommending that acupuncture needles be classified into class II, the Panel considered risks of infection and trauma from needle breakage, but not risks presented by lack of effective therapy or diagnosis. In the **Federal Register** of March 9, 1973 (38 FR 6419), FDA published a notice explaining that FDA believed that the safety and effectiveness of acupuncture devices had not yet been established by adequate scientific studies to support the many uses for which the devices were being promoted. The agency concluded that until safety and effectiveness are established, acupuncture devices would be considered misbranded if the device labeling contains any claims of therapeutic or diagnostic effectiveness, or fails to include a statement of the investigational nature of the device and certain other information. The agency has not received any information to justify a conclusion different from that announced in 1973. Thus, FDA considers acupuncture devices still to be in investigational status and not to have been in commercial distribution before the amendments, for purposes of section 513 of the act. Under section 513 (b)(1) and (f), FDA does not publish for comment proposed classification regulations for devices that were not in commercial distribution before the amendments (other than postamendments devices that are substantially equivalent to those in commercial distribution before the amendments). Proposed classification regulations are unnecessary for these devices because section 513(f) of the statute itself classifies them into class III, unless reclassified by FDA orders. Because devices classified into class III by section 513(f) of the act were not in commercial distribution before the amendments, the devices are subject immediately to the premarket approval requirements of section 515 without benefit of the statutory grace period under section 501(f)(2)(A) for preamendments class III devices and postamendments, substantially equivalent devices.

The agency will, at a later date, publish final regulations describing the statutory class III status for certain devices so classified by section 513(f) of the act, as well as the status of devices reclassified by orders under section 513(f), and those formerly considered new drugs and classified into class III by section 520(1) of the act.

Because FDA believes that acupuncture devices should remain in investigational status until safety and effectiveness have been demonstrated, sponsors and investigators of acupuncture devices will be required to comply with the final regulation governing applications for an investigational device exemption (IDE) when that regulation is promulgated and becomes effective. A proposed IDE regulation was published in the **Federal Register** of August 20, 1976 (41 FR 35282). Upon receipt of comments, the proposed regulation was revised, and a tentative final regulation was published in the **Federal Register** of May 12, 1978 (43 FR 20726). Sponsors and investigators of acupuncture devices should be prepared to comply with the final IDE regulation when it becomes effective.

FDA also has issued proposed general regulations on the responsibilities of sponsors and monitors of clinical investigations in the **Federal Register** of September 27, 1977 (42 FR 49612); standards for investigational review boards for clinical investigations in the **Federal Register** of August 8, 1978 (43 FR 31586), reproposed in the **Federal Register** of August 14, 1979 (44 FR 47699); obligations of clinical investigators of regulated articles in the **Federal Register** of August 8, 1978 (43 FR 35210); and informed consent in the **Federal Register** of August 14, 1978 (44 FR 47713). Sponsors and investigators should refer to these proposals for additional guidance in conducting investigational studies involving acupuncture devices.

Life Supporting or Life Sustaining Devices Proposed for Classification in Class II

The Panel has identified 38 devices the Panel believes are life supporting or life sustaining devices. The Panel believes that premarket approval is unnecessary for these 38 devices. The agency agrees that some of these devices are life supporting or sustaining, but that some may not be in that category. The agency has concurred in the Panel's recommendations that these devices be classified into Class II. For each of these 38 devices, the Panel specifically found that it is unnecessary to classify the device in Class III because there is sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

Because of the unusually large number of life supporting or life sustaining devices proposed for classification in Class II, FDA believes that it is important to emphasize two features of anesthesiology and respiratory therapy devices that contribute to this result. First, anesthesiology and respiratory therapy devices are, by nature, intended for use in connection with the life supporting functions of the body. Consequently, a larger percentage of such devices are life supporting than is the case in other therapeutic categories. Second, although many devices used in anesthesiology are life supporting, the principles governing their operation are well known and accepted in the medical community. All are devices with which the members of the Panel have had sufficient experience to determine whether there is enough information to develop a performance standard to assure their safety and effectiveness. Many of the devices have been in use for decades. Many are the subject of existing performance standards written by, or standards that are currently under development by, various institutions.

Environmental Impact

FDA has carefully considered the environmental effects of proposed § 868.1 and the proposed anesthesiology device classification regulations. Because the proposed actions will not significantly affect the quality of the human environment, the agency has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration (address above).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), the Commissioner proposes that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 868, Subpart A, to read as follows:

PART 868—ANESTHESIOLOGY DEVICES

Subpart A—General Provisions

Sec.
868.1 Scope.

Authority: Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c and 701(a)).

Subpart A—General Provisions

§ 868.1 Scope.

(a) This part sets forth the classification of anethesiology devices intended for human use.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 of this chapter cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87 of this chapter.

(c) To avoid duplicative listings, and anesthesiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administation.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33334 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1649]

Medical Devices; Classification of Manual Algesimeters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying manual algesimeters into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into the class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of manual algesimeters:

1. Identification: A manual algesimeter is a mechanical device used to determine a patient's sensitivity to pain after using an anesthetic agent, e.g., by pricking with a sharp point.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempted from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that manual algesimeters be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards to control the identified risks to health. The Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirement because the good manufacturing practice regulations would not improve the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Skin trauma: Sharp edges or surface imperfections may cause trauma to the patient's skin.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that manual algesimeters be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a manual algesimeter be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21

CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a manual algesimeter must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a manual algesimeter must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 by adding new Subpart B and new § 868.1030, to read as follows:

Subpart B—Diagnostic Devices

§ 868.1030 Manual algesimeter.

(a) *Identification.* A manual algesimeter is a mechanical device used to determine a patient's sensitivity to pain after using an anesthetic agent, e.g., by pricking with a sharp point.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33335 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1650]

Medical Devices; Classification of Powered Algesimeters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered algesimeters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into the class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panal Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered algesimeters:

1. Identification: A powered algesimeter is a device using electrical stimulation to determine a patient's sensitivity to pain after administration of an anesthetic agent.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be low priority.

3. Summary of reasons for recommendation: The Panel recommends that the powered algesimeter be classified into class II (performance standards) because the design of, and the materials used in, the device must be adequate to assure that neither the patient nor the operator are shocked or burned from excessive leakage current. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panal believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this and related devices.

5. Risks to health: (a) Electrical shock: If the device is not properly designed, the patient or operator may receive an electrical shock. (b) Excessive muscle contraction: Excessive current or improper output parameters can cause the patient to have excessive muscle contractions.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that powered algesimeters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1040, to read as follows:

§ 868.1040 Powered algesimeter.

(a) *Identification.* A powered algesimeter is a device using electrical stimulation to determine a patient's sensitivity to pain after administration of an anesthetic agent.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m. Monday through Friday.

Dated: September 19, 1979.

William F. Randolph

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33336 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1651]

Medical Devices; Classification of Argon Gas Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying argon gas analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of argon gas analyzers:

1. Identification: An argon gas analyzer is a device used to measure the connection of argon in a gas mixture to aid in determining the patient's ventilatory status. The device may use techniques such as mass spectrometry or thermal conductivity.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that argon gas analyzers be classified into class II (performance standards) because the device must accurately measure the argon gas concentration to ensure that the patient's ventilatory status will be properly assessed. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the argon gas concentration may cause the patient's condition to be incorrectly diagnosed and treated.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that argon gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 by adding new Subpart B including § 868.1075, to read as follows:

SUBPART B—DIAGNOSTIC DEVICES

§ 868.1075 Argon gas analyzer.

(a) *Identification.* An argon gas analyzer is a device used to measure the concentration of argon in a gas mixture to aid in determining the patient's ventilatory status. The device may use techniques such as mass spectrometry or thermal conductivity.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33337 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1652]

Medical Devices; Classification of Arterial Blood Sampling Kits

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying arterial blood sampling kits into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The

effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of arterial blood sampling kits:

1. Identification: An arterial blood sampling kit is a device, in kit form, used to obtain arterial blood samples from a patient for blood gas determinations. The kit may include a syringe, needle, cork, and heparin.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that arterial blood sampling kits be classified into class II (performance standards) to assure that the device is sterile to prevent infection, and that the kit contains the proper amount of heparin and that the syringe does not leak, leading to inaccurate oxygen tension measurements. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inappropriate therapy: An improper amount of heparin in the syringe, or atmospheric contamination caused by leakage of the syringe, may cause errors in the measurement of arterial oxygen tension resulting in inappropriate therapy. (b) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that arterial blood sampling kits be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1100, to read as follows:

§ 868.1100 Arterial blood sampling kit.

(a) *Identification.* An arterial blood sampling kit is a device, in kit form, used to obtain arterial blood samples from a patient for blood gas determinations. The kit may include a syringe, needle, cork, and heparin.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33338 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1653]

Medical Devices; Classification of Nonindwelling Blood Carbon Monoxide Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonindwelling blood carbon monoxide analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonindwelling blood carbon monoxide analyzers:

1. Identification: A nonindwelling blood carbon monoxide analyzer is a device used to measure, in vitro, the concentration of carboxyhemoglobin (a compound formed from hemoglobin when exposed to carbon monoxide) in blood, to aid in determining the patient's physiological status.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that nonindwelling blood carbon monoxide analyzers be classified into class II (performance standards) to assure that the carboxyhemoglobin concentration in the patient's blood is accurately measured. The measurement is necessary to assess the decrease in the oxygen-carrying capacity of the patient's blood to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the patient's blood carbon monoxide concentration may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonindwelling blood carbon monoxide analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1110, to read as follows:

§ 868.1110 Nonindwelling blood carbon monoxide analyzer.

(a) *Identification.* A nonindwelling blood carbon monoxide analyzer is a device used to measure, in vitro, the concentration of carboxyhemoglobin (a compound formed from hemoglobin when exposed to carbon monoxide) in blood to aid in determining the patient's physiological status.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33339 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N–1654]

Medical Devices; Classification of Indwelling Blood Oxyhemoglobin Concentration Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying indwelling blood oxyhemoglobin concentration analyzers into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1979. FDA propses that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of indwelling blood oxyhemoglobin concentration analyzers:

1. Identification: An indwelling blood oxyhemoglobin concentration analyzer is a photoelectric device used to measure, in vivo, the oxygen-carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that indwelling the blood oxyhemoglobin concentration analyzers be classified into class III (premarket approval) because the device presents a potential unreasonable risk of illness or injury to the patient. The Panel believes that insufficient information exists to determine that general controls or standards would be adequate to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the lack of published clinical data relating to the safety of, and the problems associated with this device, and on the lack of widespread clinical experience in using the device.

5. Risks to health: (a) inappropriate therapy: Inaccurate measurement of the blood oxyhemoglobin concentration may cause an incorrect diagnosis.

leading to inappropriate therapy. (b) Thrombus or embolus formation: If the analyzer materials are incompatible with the blood, thrombus or embolus (clot) formation may result. (c) Electrical shock: If the device is not designed properly the patient may recieve an electrical shock. (d) Vascular occlusion: If the device sensor is too large, it may occlude the blood vessel in which it is placed, thus stopping blood flow through that vessel.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that indwelling blood oxyhemoglobin concentration analyzer devices be classified into class III (premarket approval). The agency believes that the device presents a potential unreasonable risk of illness or injury because the design of, and the materials used in, the device may contribute to thrombus or embolus formation, and because erroneous oxyhemoglobin concentration measurements may lead to institution of inappropriate patient therapy. The agency also believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1120 as follows:

§ 868.1120 Indwelling blood oxyhemoglobin concentration analyzer.

(a) *Identification.* An indwelling blood oxyhemoglobin concentration analyzer is a photoelectric device used to measure, in vivo, the oxygen-carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33340 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1655]

Medical Devices; Classification of Nonindwelling Blood Oxyhemoglobin Concentration Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonindwelling blood oxyhemoglobin concentration analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonindwelling blood oxyhemoglobin concentration analyzers:

1. Identification: A nonindwelling blood oxyhemoglobin concentration analyzer is a device used to measure, in vitro, the oxygen-carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that nonindwelling blood oxyhemoglobin concentration analyzers be classified into class II (performance standards) because the accurate measurement of the patient's blood oxyhemoglobin concentration to assess its oxygen-carrying capacity is necessary to assure proper patient diagnosis. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, nonindwelling blood oxyhemoglobin concentration analyzers.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the blood exyhemoglobin concentration in a blood sample may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonindwelling blood oxyhemoglobin concentration analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the

Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1130, to read as follows:

§ 868.1130 Nonindwelling blood oxyhemoglobin concentration analyzer.

(a) *Identification.* A nonindwelling blood oxyhemoglobin concentration anaylzer is a device used to measure, in vitro, the oxygen-carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33341 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1657]

Medical Devices; Classification of Indwelling Blood Carbon Dioxide Partial Pressure (P_{CO_2}) Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers:

1. Identification: An indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer is a device which consists of a catheter-tip P_{CO_2} transducer (e.g., P_{CO_2} electrode) that is used to measure, in vivo, the partial pressure of carbon dioxide in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendations: The Panel recommends that indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers be classified into class III (premarket approval) because the device presents a potential unreasonable risk of illness or injury to the patient. The Panel also believes that insufficient information exists to determine that general controls or standards would be adequate to provide reasonable assurance of safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the lack of published clinical data, relating to the safety of, and the problems associated with, this device, and on the lack of widespread clinical experience with the device.

5. Risks to health: (a) Inappropriate therapy: If the device is improperly calibrated, the P_{CO_2} measurement may be erroneous, causing an incorrect diagnosis that leads to inappropriate therapy. (b) Thrombus and embolus formation: The analyzer materials may be incompatible with the blood, causing thrombus and embolus (clot) formation. (c) Electrical shock: If the device is improperly designed, users may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers be classified into class III (premarket approval). The agency believes that the device presents a potential unreasonable risk of illness or injury because the design of, and the materials used in, the device may contribute to thrombus or embolus formation and erroneous P_{CO_2} measurements may lead to inappropriate patient therapy. The agency believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1150, to read as follows:

§ 868.1150 Indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer.

(a) *Identification.* An indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer is a device which consists of a catheter-tip P_{CO_2} transducer (e.g., P_{CO_2} electrode) and is used to measure, in vivo, the partial pressure of carbon dioxide in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading

of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33342 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1658]

Medical Devices; Classification of Nonindwelling Blood Carbon Dioxide Partial Pressure (P_{CO_2}) Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers:

1. Identification: A nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer is a device used to measure, in vitro, the partial pressure of carbon dioxide in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status. The device may use techniques such as chemical titration, electrochemical methods, or mass spectrometry.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers be classified into class II (performance standards) because the partial pressure of carbon dioxide in a patient's blood must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the partial pressure of carbon dioxide in the patient's blood may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1160, to read as follows:

§ 868.1160 Nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer.

(a) *Identification.* A nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer is a device used to measure, in vitro, the partial pressure of carbon dioxide in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status. The device may use techniques such as chemical titration, electrochemical methods, or mass spectrometry.

(b) *Classification.* Class II (performance standards). Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33343 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1659]

Medical Devices; Classification of Indwelling Blood Hydrogen Ion Concentration (pH) Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying indwelling blood hydrogen ion concentration (pH) analyzers into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class III and the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket

approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides backgroud information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the Cardiovascular Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of indwelling blood hydrogen ion concentration (pH) analyzers:

1. Identification: An indwelling blood hydrogen ion concentration (pH) analyzer is a device which consists of a catheter-tip pH electrode that is used to measure, in vivo, the hydrogen ion concentration (pH) in blood to aid in determining the patient's acid-base balance.

2. Recommended Classification: The Anesthesiology Device classification Panel recommends that indwelling blood hydrogen ion concentration analyzers be classified in Class III (premarket approval). The Anesthesiology Device Classification Panel recommends that premarket approval of this device be a medium priority. The Cardiovascular Device Classification Panel recommends that the device be classified in Class II (performance standards). The Cardiovascular Panel recommends that establishing performance standards be a low priority.

3. Summary of reasons for recommendation: The Anesthesiology Device Classification Panel recommends that indwelling blood hydrogen ion concentration (pH) analyzers be classified into class III (premarket approval) because the device presents a potential unreasonable risk of illness or injury to the patient. The Panel believes that insufficient information exists to determine that general controls or standards would be adequate to provide reasonable assurance of the safety and effectiveness of the device. The Cardiovascular Device Classification Panel recommends that the pH catheter probe be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the blood stream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Certain performance characteristics of the pH catheter probe, such as electrical isolation, accuracy, and stability, should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard would provide reasonable assurance of safety and effectivenss of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Anesthesiology Device Classification Panel based its recommendation on the lack of published clinical data relating to the safety of, and the problems associated with, this device, and on the lack of widespread clinical experience in using the device. The Cardiovascular Device Classification Panel based its recommendation on the potential hazards associated with the inherent properties of the device and on the Panel members knowledge of, and clinical experience with, the device.

5. Risks to health: Both the Anesthesiology Device Classification Panel and the Cardiovascular Device Classification Panel identified the following risks to health: (a) Inappropriate therapy: If the device is improperly calibrated, erroneous pH measurements may cause an incorrect diagnosis, leading to inappropriate therapy. (b) Thrombus or embolus formation: The analyzer materials may be incompatible with the blood, leading to thrombus on embolus (clot) formation. (c) Electrical shock: If the device is improperly designed, the patient may receive an electrical shock.

Proposed Classification

FDA agrees with the Anesthesiology Device Classification Panel recommendation and is proposing that indwelling blood hydrogen ion concentration (pH) analyzers be classified into class III (premarket approval). FDA disagrees with the Cardiovascular Device Classification Panel recommendation that indwelling blood hydrogen ion concentration (pH) analyzers be classified into class II (performance standards). The agency believes the device presents a potential unreasonable risk of illness or injury because the design of, and the materials used in the device may contribute to thrombus or embolus formation and because erroneous pH mesurement may lead to inappropriate patient therapy. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1170, to read as follows:

§ 868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.

(a) *Identification.* An indwelling blood hydrogen ion concentration (pH) analyzer is a device which consists of a catheter-tip pH electrode that is used to measure, in vivo, the hydrogen ion concentration (pH) in blood to aid in determining the patient's acid-base balance.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980, submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600

Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33344 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1660]

Medical Devices; Classification of Nonindwelling Blood Hydrogen Ion Concentration (pH) Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonindwelling blood hydrogen ion concentration (pH) analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulations. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonindwelling blood hydrogen-ion concentration (pH) analyzers:

1. Identification: A nonindwelling blood hydrogen ion concentration (pH) analyzer is a device that uses electrochemical electrodes to measure, in vitro, the hydrogen ion concentration of blood to aid in determining the patient's acid-base balance.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reason for recommendation: The Panel recommends that nonindwelling blood hydrogen ion concentration (pH) analyzers be classified into class II (performance standards) because the patient's blood pH must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's person knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the blood hydrogen ion concentration (pH) may cause an incorrect diagnosis, leading to inappropriate therapy.

Propose Classification

FDA agrees with the Panel recommendation and is proposing that nonindwelling blood hydrogen ion concentration (pH) analyzers be classified into class II. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1180, to read as follows:

§ 868.1180 Nonindwelling blood hydrogen ion concentration (pH) analyzer.

(a) *Identification.* A nonindwelling blood hydrogen ion concentration (pH) analyzer is a device that uses electrochemical electrodes to measure, in vitro, the hydrogen ion concentration of blood to aid in determining the patient's acid-base balance.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randloph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33345 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1661]

Medical Devices; Classification of Nonindwelling Blood Nitrogen Partial Pressure (PN_2) Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying non-indwelling blood nitrogen partial pressure (PN_2) analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards

to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonindwelling blood nitrogen partial pressure (PN_2) analyzers:

1. Identification: A nonindwelling blood nitrogen partial pressure (PN_2) analyzer is a device used to measure, in vitro, the partial pressure of nitrogen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that nonindwelling blood nitrogen partial pressure (PN_2) analyzers be classified into class II (performance standards) because the partial pressure of nitrogen in a patient's blood must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, nonindwelling blood nitrogen partial pressure (PN_2) analyzers.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the partial pressure of nitrogen in the patient's blood may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonindwelling blood nitrogen partial pressure (PN_2) analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under the authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1190, to read as follows:

§ 868.1190 Nonindwelling blood nitrogen partial pressure (PN_2) analyzer.

(a) *Identification.* A nonindwelling blood nitrogen partial pressure (PN_2) analyzer is a device used to measure, in vitro, the partial pressure of nitrogen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33346 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1662]

Medical Devices; Classification of Indewelling Blood Oxygen Partial Pressure (P_{o_2}) Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying indwelling blood oxygen partial pressure (P_{o_2}) analyzers into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel, the General and Plastic Surgery Device Classification Panel, and the General Hospital and Personal Use Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation.

The Anesthesiology Device Classification Panel, the General and Plastic Surgery Device Classification Panel, and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of indwelling blood oxygen partial pressure (P_{o_2}) analyzers:

1. Identification: An indwelling blood oxygen partial pressure (P_{o_2}) analyzer is a device which consists of a catheter-tip P_{o_2} transducer (e.g., P_{o_2} electrode) that is used to measure, in vivo, the partial pressure of oxygen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

2. Recommended classification: Class III (premarket approval). The Anesthesiology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic Surgery Device Classification Panel recommend that indwelling blood oxygen partial pressure (P_{o_2}) analyzers be classified into class III (premarket approval). The Anesthesiology Device Classification Panel recommends that premarket approval of this device be a medium priority. The General Hospital Device Classification Panel and the General and Plastic Surgery Device Classification Panel recommend that premarket approval of this device be a high priority. .

3. Summary of reasons for recommendation: The Anesthesiology Device Classification Panel recommends that indwelling blood oxygen partial pressure (P_{o_2}) analyzers be classified into class II because the device presents a potential unreasonable risk of illness or injury. The Panel believes that insufficient information exists to determine that general controls or performance standards would be adequate to provide reasonable assurance of the safety or effectiveness of the device. The General Hospital and Personal Use Device Classification Panel cited insufficient information concerning the device and the potential for misdiagnosis of P_{o_2} as reasons for recommending classification into class III. The General and Plastic Surgery Device Classification Panel cited the high incidence of blood clot formation resulting from use of the device and insufficient information to establish an adequate performance standards for the device as reasons for its recommendation that the device be classified into class III.

4. Summary of data on which the recommendation is based: The Anesthesiology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic Surgery Device Classification Panel based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device. The Panels also based their recommendations on the lack of published clinical data available relating to the safety of, and the problems associated with, this device, and on the lack of widespread clinical experience in using the device.

5. Risks to health: Both the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel identified the following risks to health: (a) Inappropriate therapy: If the deivce is improperly calibrated, erroneous measurement of the blood P_{o_2} may cause an incorrect diagnosis of the patient's condition, leading to inappropriate therapy. (b) Embolus formation: Analyzer materials may be incompatible with the blood, causing thrombus or embolus formation. (c) Bleeding: The P_{o_2} analyzer may puncture the blood vessel, resulting in potentially fatal bleeding. (d) Electrical shock: If the device is improperly designed, the patient may receive an electrical shock. In addition to the foregoing, the General and Plastic Surgery Device Classification Panel identified the following risks to health: (e) Infection: If the device is not sterile, infection may result. (f) Bleeding: Poor mechanical integrity of the catheter-electrode components may cause them to disassemble accidentally, resulting in severe blood loss from the patient.

Proposed Classification

FDA agrees with the Panels' recommendations and is proposing that indwelling blood oxygen partial pressure (P_{o_2}) analyzers be classified into class III (premarket approval). The agency believes the device presents a potential unreasonable risk of illness or injury because the design of, and the materials used in, the device may contribute to thrombus or embolus formation and because erroneous blood oxygen partial pressure measurements may lead to institution of inappropriate patient therapy. The agency believes that premarket approval is necessary for this device because general controls or performance standards are insufficient to control the above described risks to health and thus cannot provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1200, to read as follows:

§ 868.1200 Indwelling blood oxygen partial pressure (P_{o_2}) analyzer.

(a) *Identification.* An indwelling blood oxygen partial pressure (P_{o_2}) analyzer is a device which consists of a catheter-tip P_{o_2} transducer (e.g., P_{o_2} electrode) that is used to measure, in vivo, the partial pressure of ozygen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 6500 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33347 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1663]

Medical Devices; Classification of Nonindwelling Blood Oxygen Partial Pressure (P_{o_2}) Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonindwelling blood oxyen partial pressure (P_{o_2}) analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonindwelling blood oxygen partial pressure (P_{O_2}) analyzers:

1. Identification: A nonindwelling blood oxygen partial pressure (P_{O_2}) analyzer is a device used to measure, in vitro, the partial pressure of oxygen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status. The device may use techniques such as electrochemical electrodes, gas chromatography, or mass spectrometry.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that nonindwelling blood oxygen partial pressure (P_{O_2}) analyzers be classified into class II (performance standards) because the partial pressure of oxygen in a patient's blood must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the partial pressure of oxygen in the patient's blood may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonindwelling blood oxygen partial pressure (P_{O_2}) analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1210, to read as follows:

§ 868.1210 Nonindwelling blood oxygen partial pressure (P_{O_2}) analyzer.

(a) *Identification.* A nonindwelling blood oxygen partial pressure (P_{O_2}) analyzer is a device used to measure, in vitro, the partial pressure of oxygen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status. The device may use techniques such as electrochemical electrodes, gas chromatography, or mass spectrometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33348 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N–1664]

Medical Devices; Classification of Calibrated Breathing System Collection Bottles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying calibrated breathing system collection bottles into class II (performance standards). The FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of calibrated breathing system collection bottles:

1. Identification: A calibrated breathing system collection bottle is a calibrated container that is used to collect fluids aspirated from a patient and that is capable of protecting the vacuum source by stopping the vacuum when the container overflows.

2. Recommended classification: Class II (performance standards). The Panel

recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the calibrated breathing system collection bottle be classified into class II (performance standards) to assure that the graduations on the bottle are correctly calibrated. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inaccurate measurement: Inaccurate graduations on the bottle will cause inaccurate measurement of the volume of aspirated fluid. (b) Inadequate suction: Inadequate sealing of the bottle will decrease its effectiveness, due to air leakage. (c) Contamination of main vacuum system: Failure of the automatic cutoff may result in contamination of the main vacuum system, increasing the risk of patient infections.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that calibrated breathing system collection bottles be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1250. to read as follows:

§ 868.1250 Calibrated breathing system collection bottle.

(a) *Identification.* A calibrated breathing system collection bottle is a calibrated container that is used to collect fluids aspirated from a patient and that is capable of protecting the vacuum source by stopping the vacuum when the container overflows.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33349 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1665]

Medical Devices; Classification of Uncalibrated Breathing System Collection Bottles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying uncalibrated breathing system collection bottles into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of uncalibrated breathing system collection bottles:

1. Identification: An uncalibrated breathing system collection bottle is a container that is used to collect fluids aspirated from a patient and that is capable of protecting the vacuum source by stopping the vacuum when the container overflows.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that uncalibrated breathing system collection bottles be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards to control the identified risks to health. The Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements because compliance with those requirements would not improve the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inadequate suction: Inadequate sealing of the bottle will decrease its effectiveness due to air leakage. (b) Contamination of the main vacumm system: Failure of the automatic cutoff may result in contamination of the main vacumm system, increasing the risk of patient infections.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that uncalibrated breathing system collection bottles be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of an uncalibrated breathing system collection bottle be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820. 198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of an uncalibrated breathing system collection bottle must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigations and followup. The agency also believes that manufacturers of an uncalibrated breathing system collection bottle must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1260, to read as follows:

§ 868.1260 Uncalibrated breathing system collection bottle.

(a) *Identification.* An uncalibrated breathing system collection bottle is a container that is used to collect fluids aspirated from a patient and that is capable of protecting the vacuum source by stopping the vacuum when the container overflows.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33350 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1666]

Medical Devices; Classification of Carbon Dioxide Gas Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carbon dioxide gas analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of carbon dioxide gas analyzers:

1. Identification: A carbon dioxide gas analyzer is a device used to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory, circulatory, and metabolic status. The device may use techniques such as chemical titration, absorption of infrared radiation, gas chromatography, and mass spectrometry.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that carbon dioxide gas analyzers be classified into class II (performance standards) because the carbon dioxide concentration in a patient's breath must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the carbon dioxide concentration may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that carbon dioxide gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1400, as follows:

§ 868.1400 Carbon dioxide gas analyzer.

(a) *Identification.* A carbon dioxide gas analyzer is a device used to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory, circulatory, and metabolic status. The device may use techniques such as chemical titration, absorption of infrared radiation, gas chromatography, and mass spectrometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33351 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1667]

Medical Devices; Classification of Carbon Monoxide Gas Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carbon monoxide gas analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of carbon monoxide gas analyzers:

1. Identification: A carbon monoxide gas analyzer is a device used to measure the concentration of carbon monoxide in a gas mixture to aid in determining the patient's ventilatory status. The device may use techniques such as infrared absorption and gas chromatography.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that carbon monoxide gas analyzers be classified into class II (performance standards) because the carbon monoxide concentration in a patient's breath must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the carbon monoxide concentration in a gas mixture may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that carbon monoxide gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1430, to read as follows:

§ 868.1430 Carbon monoxide gas analyzer.

(a) *Identification.* A carbon monoxide gas analyzer is a device used to measure the concentration of carbon monoxide in a gas mixture to aid in determining the patient's ventilatory status. The device may use techniques such as infrared absorption and gas chromatography.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be

identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33352 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1668]

Medical Devices; Classification of Enflurane Gas Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying enflurane gas analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of enflurane gas analyzers:

1. Identification: An enflurane gas analyzer is a device used to measure the concentration of enflurane anesthetic in a gas mixture.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the enflurane gas analyzer be classified into class II (performance standards) because the device must accurately measure the concentration of enflurane anesthetic in a gas mixture to assure that the patient is properly anesthetized. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Memory and pain: If the device's calibration is faulty and the patient receives too low a concentration of enflurane to be properly anesthetized, the patient may experience pain during surgery and remember the surgery afterwards. (b) Cardiopulmonary arrest: Excessive depth of anesthesia caused by faulty calibration may induce cardiopulmonary arrest and possibly death.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that enflurane gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1500, to read as follows:

§ 868.1500 Enflurane gas analyzer.

(a) *Identification.* An enflurane gas analyzer is a device used to measure the concentration of enflurane anesthetic in a gas mixture.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33353 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78-1669]

Medical Devices; Classification of Gas Collection Vessels

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas collection vessels into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-

65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas collection vessels:

1. Identification: A gas collection vessel is a containerlike device used to collect a patient's exhaled gases for subsequent analysis. It does not include a sampling pump.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas collection vessels be classified into calss II (performance standards) because the design of, and the materials used in, the device must be controlled to assure that the patient's exhaled gases are sampled properly and to prevent gas leaks or absorption of the sampled gas in the device. Improper sampling or sample storage may result in an inaccurate analysis of the sampled gases that could cause an incorrect diagnosis, leading to inappropriate therapy. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: System leaks or absorption of the sampled gas in the device may result in the inaccurate measurement of the sampled gas. The inaccurate measurement may cause an incorrect diagnosis of the patient's condition, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas collection vessels be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1575, to read as follows:

§ 868.1575 Gas collection vessel.

(a) *Identification.* A gas collection vessel is a container-like device used to collect a patient's exhaled gases for subsequent analysis. It does not include a sampling pump.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Land, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33354 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1670]

Medical Devices; Classification of Halothane Gas Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying halothane gas analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of halothane gas analyzers:

1. Identification: A halothane gas analyzer is a device used to measure the concentration of halothane anesthetic in a gas mixture. The device may use techniques such as mass spectrometry or absorption of infrared and ultraviolet radiation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that halothane gas analyzers be classified into class II (performance standards) because the device must accurately measure the concentration of halothane anesthetic in a gas mixture to assure that the patient is properly anesthetized. The Panel believes that general controls will not

provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Memory and pain: If the device's calibration is faulty and the patient receives too low a concentration of halothane to be properly anesthetized, the patient may experience pain during surgery and/or remember the surgery afterwards. (b) Cardiopulmonary arrest: Excessive depth of anesthesia caused by faulty calibration, may induce cardiopulmonary arrest and possible death.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that halothane gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1620, to read as follows:

§ 868.1620 Halothane gas analyzer.

(a) *Identification.* A halothane gas analyzer is a device used to measure the concentration of halothane anesthetic in a gas mixture. The device may use techniques such as mass spectrometry or absorption of infrared and ultraviolet radiation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33355 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1671]

Medical Devices; Classification of Helium Gas Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying helium gas analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of helium gas analyzers:

1. Identification: A helium gas analyzer is a device used to measure the concentration of helium in a gas mixture during pulmonary function testing. The device may use techniques such as thermal conductivity, gas chromatography, or mass spectrometry.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the helium gas analyzers be classified into class II (performance standards) because the helium concentration in a gas mixture must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the helium gas concentration may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that helium gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1640, to read as follows:

§ 868.1640 Helium gas analyzer.

(a) *Identification.* A helium gas analyzer is a device used to measure the concentration of helium in a gas mixture during pulmonary function testing. The device may use techniques such as thermal conductivity, gas chromatography, or mass spectrometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33356 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1672]

Medical Devices; Classification of Neon Gas Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying neon gas analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the furture development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of neon gas analyzers:

1. Identification: A neon gas analyzer is a device used to measure the concentration of neon in a gas mixture exhaled by a patient. The device may use techniques such as mass spectrometry or thermal conductivity.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that neon gas analyzers be classified into class II (performance standards) because the neon concentration in a gas mixture must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the neon gas concentration may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the neon gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1670, to read as follows:

§ 868.1670 Neon gas analyzer.

(a) *Identification.* A neon gas analyzer is a device used to measure the concentration of neon in a gas mixture exhaled by a patient. The device may use techniques such as mass spectrometry or thermal conductivity.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33357 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1673]

Medical Devices; Classification of Nitrogen Gas Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nitrogen gas analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of

one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nitrogen gas analyzers:

1. Identification: A nitrogen gas analyzer is a device used to measure the concentration of nitrogen in respiratory gases to aid in determining the patient's ventilatory status. The device may use techniques such as gas chromatography or mass spectrometry.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that nitrogen gas analyzers be classified into class II (performance standards) because the nitrogen concentration in a patient's breath must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the nitrogen gas concentration may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nitrogen gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1690, to read as follows:

§ 868.1690 Nitrogen gas analyzer.

(a) *Identification.* A nitrogen gas analyzer is a device used to measure the concentration of nitrogen in respiratory gases to aid in determining the patient's ventilatory status. The device may use techniques such as gas chromatography or mass spectrometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33358 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N–1674]

Medical Devices; Classification of Nitrous Oxide Gas Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nitrous oxide gas analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, An FDA advisory committee, made the following recommendation regarding the classification of nitrous oxide gas analyzers:

1. Identification: A nitrous oxide gas analyzer is a device used to measure the concentration of nitrous oxide anesthetic in a gas mixture. The device may use techniques such as infrared absorption or mass spectrometry.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that nitrous oxide gas analyzers be classified into class II (performance standards) because the device's accurancy must be adequate to assure that the patient is properly anesthetized. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Hypoxemia: Patient hypoxemia (deficient blood oxygenation) may be caused by an excessive concentration of nitrous oxide due to faulty analyzer calibration. (b) Memory and pain: If the device's calibration is faulty and causes the patient to receive too low a concentration of nitrous oxide to be properly anesthetized, the patient may experience pain during surgery and/or remember the surgery afterwards. (c) Cardiopulmonary arrest: Excessive depth of anesthesia caused by faulty analyzer calibration could lead to cardiopulmonary arrest.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nitrous oxide gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1700, to read as follows:

§ 868.1700 Nitrous oxide gas analyzer.

(a) *Identification.* A nitrous oxide gas analyzer is a device used to measure the concentration of nitrous oxide anesthetic in a gas mixture. The device may use techniques such as infrared absorption or mass spectrometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33359 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-83-M

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21 CFR Part 868

[Docket No. 78N–1675]

Medical Devices; Classification of Oxygen Gas Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oxygen gas analyzers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of oxygen gas analyzers:

1. Identification: An oxygen gas analyzer is a device used to measure the concentration of oxygen in respiratory gases by techniques such as mass spectrometry, polaragraphy, thermal conductivity, or gas chromatography. This generic type of device also includes paramagnetic analyzers.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that oxygen gas analyzers be classified into class II (performance standards) because the device should accurately display the oxygen concentration of the gases being supplied to the patient. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted that an American National Standards Institute Committee has drafted a proposed standard for this device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Hypoxia or hyperoxia: If the oxygen concentration of the gases breathed by the patient are inaccurately measured, the patient may receive too much oxygen, resulting in hyperoxia, or too little oxygen, resulting in hypoxia.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that oxygen gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health

presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1720, to read as follows:

§ 868.1720 Oxygen gas analyzer.

(a) *Identification.* An oxygen gas analyzer is a device used to measure the concentration of oxygen in respiratory gases by techniques such as mass spectrometry, polaragraphy, thermal conductivity, or gas chromatography. This generic type of device also includes paramagnetic analyzers.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33360 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1676]

Medical Devices; Classification of Oxygen Uptake Computers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oxygen uptake computers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of oxygen uptake computers:

1. Identification: An oxygen uptake computer is a device used to compute the amount of oxygen consumed by the patient and may include components for determining expired gas volume and composition.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that oxygen uptake computers be classified into class II (performance standards) because the device must accurately compute the amount of oxygen consumed by the patient. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted that the National Fire Protection Association has been involved in developing standards for this device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: In appropriate therapy: Inaccurate measurement of oxygen consumption may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the oxygen uptake computers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1730, to read as follows:

§ 868.1730 Oxygen uptake computer.

(a) *Identification.* An oxygen uptake computer is a device used to compute the amount of oxygen consumed by the patient and may include components for determining expired gas volume and composition.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33361 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N-1677]

Medical Devices; Classification of Pressure Plethysmographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying plethysmographs into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pressure plethysmographs:

1. Identification: A pressure Plethysmograph is a device used to determine a patient's airway resistance and lung volumes by measuring pressure changes while the patient is in an airtight box.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the pressure plethysmographs be classified into class II (performance standards) because the mechanical design of, the device must be controlled to assure that the patient is able to open the chamber from the inside in the event that the operator is incapacitated. The electrical design of the device must be adequate to assure that the user does not receive an electrical shock. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Suffocation: The patient may suffocate if unable to open the chamber from the inside in the event that the operator is incapacitated. (b) Electrical shock: If the device is not designed properly, the user may recieve an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that pressure plethysmographs be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1750, to read as follows:

§ 868.1750 Pressure plethysmograph.

(a) *Identification.* A pressure plethysmograph is a device used to determine a patient's airway resistance and lung volumes by measuring pressure changes while the patient is in an airtight box.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33362 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1678]

Medical Devices; Classification of Volume Plethysmographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying volume plethysmographs into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of volume plethysmographs:

1. Identification: A volume plethysmograph is an airtight box, in which the patient sits, that is used to determine the patient's lung volume changes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standards for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that volume plethysmographs be classified into class II (performance standards) because the mechanical design of the device must be controlled to assure that the patient is able to open the chamber from the inside in the vent that the operator is incapacitated. The electrical design of the device must be adequate to assure that the user does not receive an electrical shock. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Suffocation: The patient may suffocate if unable to open the chamber from the inside in the event that the operator is incapacitated. (b) Electrical shock: If the device is not properly designed, the user may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that volume plethysmographs be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1760, to read as follows:

§ 868.1760 Volume plethysmograph.

(a) *Identification.* A volume plethysmograph is an airtight box, in which the patient sits, that is used to determine the patient's lung volume changes.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33363 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1679]

Medical Devices; Classification of Inspiratory Airway Pressure Meters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying inspiratory airway pressure meters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of inspiratory airway pressure meters:

1. Identification: An inspiratory airway pressure meter is a device used to measure the amount of pressure produced in a patient's airway during maximal inspiration.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that inspiratory airway pressure meters be classified into class II (performance standards) because the device must accurately measure a patient's inspiratory pressure. The design of, and the materials used in, the device must be controlled to prevent asphyxiation of the patient. In addition, there must be assurance that the device can be cleaned and sterilized to prevent infection due to contamination of the device. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Asphyxia: Improper design or use of this device may cause asphyxiation of the patient. (b) Inappropriate therapy: Inaccurate calibration or inspiratory pressure measurement may cause an incorrect diagnosis, leading to inappropriate therapy. (c) Patient infection: If the device is not cleaned or sterilized properly, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that inspiratory airway pressure meters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1780, to read as follows:

§ 868.1780 Inspiratory airway pressure meter.

(a) *Identification.* An inspiratory airway pressure meter is a device used to measure the amount of pressure produced in a patient's airway during maximal inspiration.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33364 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N–1680]

Medical Devices; Classification of Rhinoanemometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rhinoanemometers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into the class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panal Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rhinoanemometers:

1. Identification: A rhinoanemometer is a device used to quantify the amount of nasal congestion by measuring the airflow through, and differential pressure across, a patient's nasal passages.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be low priority.

3. Summary of reasons for recommendation: The Panel recommends that rhinoanemometers be classified into class II (performance standards) because the device design must be controlled to assure that is accurately measures the degree of nasal congestion. The Anesthesiology Device Classification Panel recommended at its August 16, 1977 meeting that this device be classified into class I (general controls) because, at that time, the Panel believed that general controls were sufficient to assure the safety and effectiveness of the device. However, during its January 24, 1978 meeting, the Panel reconsidered its original decision, and recommended that the device be classified into class II because the device provides a quantifiable output that must be accurate. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' review of the literiature on this device (Refs. 1 and 2), and on the Panel members' knowldge of related devices (i.e., pneumotachometers and differential pressure transducers).

5. Risks to health: (a) Injury: Sharp edges or other poor design characteristics may cause trauma upon insertion of the device. (b) Inappropriate therapy: Inaccurate determination of gas flow and pressure may cause the patient's condition to be incorrectly diagnosed, resulting in inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rhinoanemometers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by

interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Kern, E. B., "Rhinoanemometry," *Otolaryngologic Clinics of North America*, 6(3): 863–874, 1973.

2. Undritz, W., "The Rhinoanemometer," *Acta Laryngolic*, 14: 513–524, 1930.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1800, to read as follows:

§ 868.1800 Rhinoanemometer.

(a) *Identification.* A rhinoanemometer is a device used to quantify the amount of nasal congestion by measuring the airflow through, and differential pressure across, a patient's nasal passages.

b. *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33365 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1681]

Medical Devices; Classification of Diagnostic Spirometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying diagnostic spirometers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of diagnostic spirometers:

1. Identification: A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in and/or out of the patient's lungs.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that diagnostic spirometers be classified into class II (performance standards) because the device must generate accurate ventilatory volume or flow data, and because the design of, and the materials used in, the device must be controlled to assure that the device can be disinfected to prevent contamination and infection of patients. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel considered the 1976 American Thoracic Society (ATS) pulmonary spirometry standard (Ref. 1).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, diagnostic spirometers. These devices have been widely used for many years.

5. Risks to health: (a) Inappropriate therapy: Inaccurate measurement of ventilatory flow data may cause an incorrect diagnosis, leading to inappropriate therapy. (b) Infection: Inability to disinfect the device may result in contamination and infection of patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the diagnostic spirometers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. American Thoracic Society, Pulmonary Spirometry Standard, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1840, to read as follows:

§ 868.1840 Diagnostic spirometer.

(a) *Identification.* A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in and/or out of the patient's lungs.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may

submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33366 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1682]

Medical Devices; Classification of Monitoring Spirometers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying monitoring spirometers into class II (performance standards). The FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of monitoring spirometers:

1. Identification: A monitoring spirometer is a device used to measure continuously a patient's tidal volume (volume of gas inhaled by the patient during each respiration cycle) or minute volume (the tidal volume multiplied by the rate of respiration for 1 minute) for the evaluation of the patient's ventilatory status.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that spirometers be classified into class II (performance standards) because this device must accurately measure a patient's tidal and minute volume and because the design of, and the materials used in, the device must be controlled to assure that it can be adequately cleaned and disinfected and that it will not cause a fire or explosion if use with oxygen or inflammable agents. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted that certain sections of National Fire Protection Association Standards would apply to this device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inappropriate therapy: Inaccurate measurement of tidal and minute volume may cause an incorrect diagnosis, leading to inappropriate therapy.

(b) Infection: Inability to disinfect the device may result in contamination and infection of patients.

(c) Burns and trauma: Use of oxygen or other inflammable agents in a spirometer not designed for such use may cause a fire or explosion.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that monitoring spirometers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1850, to read as follows:

§ 868.1850 Monitoring spirometer.

(a) *Identification.* A monitoring spirometer is a device used to measure continuously a patient's tidal volume (volume of gas inhaled by the patient during each respiration cycle) or minute volume (the tidal volume multiplied by the rate of respiration for 1 minute) for the evaluation of the patient's ventilatory status.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33367 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1683]

Medical Devices; Classification of Peak-Flow Meters for Spirometry

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying peak-flow meters for spirometry into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The

effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of peak-flow meters for spirometry:

1. Identification: A peak-flow meter for spirometry is a device used to measure a patient's maximum ventilatory flow rate.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that peak-flow meters for spirometry be classified into class II (performance standards) because the design of, and the materials used in, the device must be controlled to assure that the device does not generate misleading flow-rate data due to an obstruction or excessive resistance in the device, and to assure that the device can be adequately sterilized to prevent infection. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inappropriate therapy: Inaccurate measurement of maximum ventilatory flow rate may cause an incorrect diagnosis, leading to inappropriate therapy. (b) Infection: If the device is not sterilized properly, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the peak-flow meters for spirometry be classified into class II (performance standards). The agency believes that a performance standards is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1860, to read as follows:

§ 868.1860 Peak-flow meter for spirometry.

(a) *Identification.* A peak-flow meter for spirometry is a device used to measure a patient's maximum ventilatory flow rate.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33368 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1684]

Medical Devices; Classification of Gas Volume Calibrators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas volume calibrators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas volume calibrators:

1. Identification: A gas volume calibrator is a device that is used to calibrate the output of gas volume

measurement instrumentation by delivering a known gas volume.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas volume calibrators be classified into class II (performance standards) because the device's accuracy must be adequate to assure proper calibration of spirometers and other gas measurement equipment. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Improper calibration of gas measurement equipment may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas volume calibrators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1870, to read as follows:

§ 868.1870 Gas volume calibrator.

(a) *Identification.* A gas volume calibrator is a device that is used to calibrate the output of gas volume measurement instrumentation by delivering a known gas volume.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33369 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1685]

Medical Devices; Classification of Pulmonary-Function Data Calculators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pulmonary-function data calculators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pulmonary-function data calculators:

1. Identification: A pulmonary-function data calculator is a device used to calculate pulmonary-function values based on actual physical data obtained during pulmonary-function testing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that pulmonary-function data calculators be classified into class II (performance standards) because the calculated pulmonary-function values must be accurate to assure proper diagnosis of the patient's conditions. The Panel recommends that the standard require that the labeling for pulmonary-function data calculators include the equations used for calculations of data. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, pulmonary-function data calculators.

5. Risks to health: Inappropriate therapy: Inaccuracies in the calculated pulmonary-function values may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that pulmonary-function data calculators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient

information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1880, to read as follows:

§ 868.1880 Pulmonary-function data calculator.

(a) *Identification.* A pulmonary-function data calculator is a device used to calculate pulmonary-function values based on actual physical data obtained during pulmonary-function testing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33370 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1686]

Medical Devices; Classification of Predictive Pulmonary-Function Value Calculators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying predictive pulmonary-function value calculators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into the class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of predictive pulmonary-function value calculators:

1. Identification: A predictive pulmonary-function value calculators is a device used to calculate normal pulmonary-function value based on empirical equations.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the predictive pulmonary-function value calculators be classified into class II (performance standards) because the predicted pulmonary-function values must be accurate to assure proper diagnosis of the patient's condition. The Panel recommends that the standard require that the labeling for the device include the empirical equations used for calculation of data. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Inappropriate therapy: Inaccurancies in the calculation of predicted pulmonary function values may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that predictive pulmonary-function value calculators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1890, to read as follows:

§ 868.1890 Predictive pulmonary-function value calculator.

(a) *Identification.* A predictive pulmonary-function value calculator is a device used to calculate normal pulmonary-function values based on empirical equations.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857; written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33371 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N-1687]

Medical Devices; Classification of Diagnostic Pulmonary-Function Interpretation Calculators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying diagnostic pulmonary-function interpretation calculators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (JFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of diagnostic pulmonary-function interpretation calculators:

1. Identification: A diagnostic pulmonary-function interpretation calculator is a device that interprets pulmonary study data to determine the clinical significance of pulmonary-function values.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the diagnostic pulmonary-function interpretation calculators be classified into class II (performance standards) because accurate interpretation of pulmonary-function data by the device is necessary to assure the proper diagnosis of the patient's condition. The Panel recommends that the standard require that the labeling for the device include the interpretation method used for the calculations of data. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Inappropriate therapy: Inaccurate interpretation of pulmonary-function data may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that diagnostic pulmonary-function interpretation calculators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1900, to read as follows:

§ 868.1900 Diagnostic pulmonary-function interpretation calculator.

(a) *Identification.* A diagnostic pulmonary-function interpretation calculator is a device that interprets pulmonary study data to determine the clinical significance of pulmonary-function values.

(b) *Classificaiton.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33372 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1688]

Medical Devices; Classification of Esophageal Stethoscopes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying esophageal stethoscopes into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia

Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of esophageal stethoscopes:

1. Identification: An esophageal stethoscopes is an unpowered device that is inserted into the patient's esophagus to enable the user to listent to heart and breath sounds.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that esophageal stethoscopes be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards to control the identified risks to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Injury: Improper size or shape of the device, or the use of improper materials in the device may result in trauma to the patient's airways or esophagus when the device is inserted. (b) Infection: If the device is not sterilized properly, infection may result.

Proposed Classification

FDA agrees with the Panel recommendations and is proposing that esophageal stethoscopes be classified into class I (general controls), with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1910, to read as follows:

§ 868.1910 Esophageal stethoscope.

(a) *Identification.* An esophageal stethoscope is an unpowered device that is inserted into the patient's esophagus to enable the user to listen to heart and breath sounds.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackers in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

FR Doc. 79–33373 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1689]

Medical Devices; Classification of Esophageal Stethoscopes With Electrical Conductors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying esophageal stethoscopes with electrical conductors into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation clasifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of esophageal stethoscopes with electrical conductors:

1. Identification: An esophageal stethoscope with electrical conductors is a device that is inserted into the esophagus to listen to heart and breath sounds and to monitor electrophysiological signals. The device may also incorporate a thermistor for temperature measurement.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the esophageal stethoscope with electrical conductors be classified into class II (performance standards) because the electrical design of the device must be adequate to assure that the patient does not receive an electrical shock or burn and because the size, shape, and materials of the device must be controlled to assure that the patient's airways and esophagus are not damaged. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Burns and electrical shock: Improper design of the device may result in the patient receiving an electrical shock or burn. (b) Injury: Improper size or shape of the device, or the use of improper materials in the device, may result in trauma to

the patient's airways or esophagus when the device is inserted. (c) Infection: if the device is not sterilized properly, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the esophageal stethoscopes with electrical conductors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1920, to read as follows:

§ 868.1920 Esophageal stethoscope with electrical conductors.

(a) *Identification.* An esophageal stethoscope with electrical conductors is a device that is inserted into the esophagus to listen to heart and breath sounds and to monitor electrophysiological signals. The device may also incorporate a thermistor for temperature measurement.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33374 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N–1690]

Medical Devices; Classification of Stethoscope Heads

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying stethoscope heads into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Devise Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of stethoscope heads:

1. Identification: A stethoscope head is a weighted chest piece used during anesthesia to listen to heart, breath and other physiological sounds.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from good manufacturing practice regulation under section 520(f) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that stethoscope heads be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements because any defects in the device are readily detectable.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Skin trauma. The patient's skin may be injured if the chest piece has sharp edges.

Proposed Classification

FDA agrees with the Panel and is proposing that stethoscope heads be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a stethoscope head be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a stethoscope head must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a stethoscope head must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1930, to read as follows:

§ 868.1930 Stethoscope head.

(a) *Identification.* A stethoscope head is a weighted chest piece used during anesthesia to listen to heart, breath, and other physiological sounds.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33375 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1691]

Medical Devices; Classification of Switching Valves (Ploss)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying switching valves (ploss) into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of switching valves (ploss):

1. Identification: A switching valve (ploss) is a three-way valve located between a stethoscope placed over the heart, a blood pressure cuff, and an earpiece. The valve allows the user to eliminate one sound channel and listen to only heart or korotoff (blood pressure) sounds through the other channel.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that switching valves (ploss) be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements because any defects in the device are readily detectable.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that switching valves (ploss) be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a switching valve (ploss) be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufactureres of a switching valve (ploss) must still be required to comply with the complaint file requirments of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a switching valve (ploss) must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1965, to read as follows:

§ 868.1965 Switching valve (ploss).

(a) *Identification.* A switching valve (ploss) is a three-way valve located between a stethoscope placed over the heart, a blood pressure cuff, and an earpiece. The valve allows the user to eliminate one sound channel and listen

to only heart of korotkoff (blood pressure) sounds through the other channel.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33376 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1692]

Medical Devices; Classification of Water Vapor Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying water vapor analyzers into class II (performance standards). The FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of water vapor analyzers:

1. Identification: A water vapor analyzer is a device used to measure the concentration of water vapor in a patient's expired gases by using techniques such as mass spectrometry

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that water vapor analyzers be classified into class II (performance standards) because the water vapor concentration in a patient's breath must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Misdiagnosis: Inaccurate measurement of water vapor concentration in the expired gases may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that water vapor analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1975, to read as follows:

§ 868.1975 Water vapor analyzer.

(a) *Identification.* A water vapor analyzer is a device used to measure the concentration of water vapor in a patient's expired gases by using techniques wuch as mass spectrometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33377 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1693]

Medical Devices; Classification of Ultrasonic Air Embolism Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ultrasonic air embolism monitors into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards

to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ultrasonic air embolism monitors:

1. Identification: An ultrasonic air embolism monitor is a device used to detect air bubbles in a patient's blood stream. It may use Doppler or other ultrasonic principles.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that ultrasonic air embolism monitors be classified into class II because the Panel believes that the reliability of the device must be adequate to assure accurate detection of air emboli. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Failure to detect air emboli: If the ultrasonic air embolism monitor fails to detect air emboli, it could result in the air emboli blocking the flow of blood in the patient's blood vessels, causing serious complications or death. (b) Electrical shock: If the device is not designed properly, the patient or operator may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ultrasonic air embolism monitors be classified into class II (performance standards). The Biological Effects of Ultrasound Subcommittee of FDA's Obstetrical and Gynecological Device Classification Panel has also reviewed the possible adverse effects of diagnostic ultrasound devices. (The Subcommittee was established because of FDA's special concerns about the obstetrical use of ultrasound, based upon several studies involving laboratory animals that showed various biological effects from prenatal ultrasound exposures (Ref. 1).) The Subcommittee concluded that there is sufficient information available to establish a standard for diagnostic ultrasound devices generally (Refs. 2, 3, and 4).

In the Federal Register of February 13, 1979 (44 FR 9542), FDA published a notice of intent announcing that it is considering an action program to reduce exposure to diagnostic ultrasound as much as practicable, consistent with the need for essential diagnostic information. One action the agency will consider taking is promulgation of a performance standard under the Radiation Control for Health and Safety Act of 1978 (Pub. L. 90–602, 42 U.S.C. 2636 et seq.). The agency believes that a performance standard under the Radiation Control for Health and Safety Act is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday:

1. Stratmeyer, M. E., "Research Directions in Ultrasound Bioeffects—A Public Health View," Proceedings of a Symposium on Biological Effects and Characterization of Ultrasound Sources, HEW Publication (FDA 78–8044, 1978).

2. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB–GYN Device Classification Panel (First Meeting), Jan. 22–23, 1976.

3. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB–GYN Device Classification Panel (Second Meeting), Oct. 28, 1976.

4. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB–GYN Device Classification Panel (Third Meeting), Oct. 4, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 by adding new Subpart C and new § 868.2025, to read as follows:

Subpart C—Monitoring Devices

§ 868.2025 Ultrasonic air embolism monitor.

(a) *Identification.* An ultrasonic air embolism monitor is a device used to detect air bubbles in a patient's blood stream. It may use Doppler or other ultrasonic principles.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33378 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1694]

Medical Devices; Classification of Bourdon Gauge Flowmeter

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying bourdon gauge flowmeters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Springs, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of bourdon gauge flowmeters:

1. Identification: A bourdon gauge flowmeter is a device used in conjunction with respiratory equipment to sense gas pressure. The device is calibrated to indicate gas flow rate with the outflow open to the atmosphere.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that bourdon gauge flowmeters be classified into class II because the Panel believes that the device must accurately measure gas flow rates to assure that gases are delivered at the correct rates to the patient and/or respiratory devices. The Panel believes that general controls will not provide sufficient control over this characteristic. The panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, bourdon gauge flowmeters.

5. Risks to health: Inappropriate therapy: The patient may receive incorrect therapy if the device does not measure gas flow rates accurately.

Proposed Classification

FDA agrees with the Panel recommendation and it proposing that bourdon guage flowmeters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Comestic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2300, to read as follows:

§ 868.2300 Bourdon gauge flowmeter.

(a) *Identification.* A bourdon gauge flowmeter is a device used in conjunction with respiratory equipment to sense gas pressure. The device is calibrated to indicate gas flow rate with the outflow open to the atmosphere.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33379 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1695]

Classification of Uncompensated Thorpe Tube Flowmeters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying uncompensated thorpe tube flowmeters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of uncompensated thorpe tube flowmeters:

1. Identification: A uncompensated thorpe tube flowmeter is a device used to indicate and control gas flow rate accurately. The device includes a vertically mounted tube and is calibrated when the outlet of the flowmeter is open to the atmosphere.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that uncompensated thorpe tube flowmeters be classified into class II because the Panel believes that the device must accurately measure gas flow rates to assure that correct gas volumes and concentrations are delivered to the patient. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccuracy or a change in outlet pressure may cause the device to display incorrect flow data, resulting in the delivery of improper gas therapy to the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that uncompensated thorpe tube flowmeters be classified into class II (performance standards). The agency believes that a performance standards is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c. 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2320, to read as follows:

§ 868.2320 Uncompensated thorpe tube flowmeter.

(a) *Identification.* An uncompensated thorpe tube flowmeter is a device used to indicate and control gas flow rate accurately. The device includes a vertically mounted tube and is calibrated when the outlet of the flowmeter is open to the atmosphere.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33380 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1696]

Medical Devices; Classification of Compensated Thorpe Tube Flowmeters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying compensated thorpe tube flowmeters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the Dental Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of compensated thorpe tube flowmeters:

1. Identification: A compensated thorpe tube flowmeter is a device used to control and measure gas flow rate accurately. The device includes a vertically mounted tube, with the outlet of the flowmeter calibrated to a reference pressure.

2. Recommended classification: Class II (performance standards). Both the Anesthesiology Device Classification Panel and the Dental Device Classification Panel recommend that this device be classified into class II (performance standards). The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a medium priority. The Dental Device Classification Panel recommended that establishing a performance standard for the device be a low priority.

3. Summary of reasons for recommendation: Both the Anesthesiology Device Classification Panel and the Dental Device Classification Panel recommend that compensated thorpe tube flowmeters be classified into class II because the Panels believe that the accuracy of the device must be controled to assure that the device displays accurate gas flow rate data. The Panels believe that general controls will not provide sufficient control over the accuracy of the device. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Both Panels based their recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. The Panels noted that compensated thorpe tube flowmeters have been widely used for many years.

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risk to health: (a) Inappropriate therapy: Inaccuracy or nonlinearity may cause the device to display inaccurate flow data, resulting in the delivery of improper gas flows or other inappropriate therapy to the patient. The Dental Device Classification Panel identified the following risk to health: (b) Incorrect amount of gas delivered: Malfunction may cause an incorrect amount of anesthetic gas to be delivered to the patient.

Proposed Classification

FDA agrees with the Panels' recommendation and is proposing that compensated thorpe tube flowmeters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2340, to read as follows:

§ 868.2340 Compensated thorpe tube flowmeter.

(a) *Identification.* A compensated thorpe tube flowmeter is a device used to control and measure gas flow rate accurately. The device includes a vertically mounted tube, with the outlet of the flowmeter calibrated to a reference pressure.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33381 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1697]

Medical Devices; Classification of Gas Calibration Flowmeters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas calibration flowmeters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into the class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panal Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas calibration flowmeters:

1. Identification: A gas calibration flowmeter is a device that is used to calibrate flowmeters and accurately measure gas flow.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas calibration flowmeters be classified into class II to assure that gas flowmeters are correctly calibrated so that the data generated by them will be accurate. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Inappropriate gas concentration: Inaccurate calibration of gas flowmeters or lack of flowmeter accuracy may lead to incorrect gas flow data resulting in delivery of inappropriate and possibly hazardous breathing mixtures to the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas calibration flowmeters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2350, to read as follows:

§ 868.2350 Gas calibration flowmeter.

(a) *Identification.* A gas calibration flowmeter is a device that is used to calibrate flowmeters and accurately measure gas flow.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33382 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1698]

Medical Devices; Classification of Breathing Frequency Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breathing frequency monitors into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the General and Plastic Surgery Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of breathing frequency monitors:

1. Identification: A breathing (ventilatory) frequency monitor is a device used to measure a patient's respiratory rate. The device provides an audible or visible alarm when the respiratory rate is outside predetermined limits.

2. Recommended classification: Class II (performance standards). The Anesthesiology Device Classification Panel and the General and Plastic Surgery Device Classification Panel recommend that this device be classified into class II. The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for the recommendation: The Panels recommend that the breathing frequency monitor be classified into class II because the Panels believe that the device must accurately and reliably detect and alert users to changes in a patients's breathing frequency. The Panels believe that general controls will not provide sufficient control over these characteristics. The Panels believe that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risks to health: (a) Undetected abnormal respiratory conditions: Failure of the device or alarm may cause abnormal conditions to go undiscovered and result in serious patient injury or death. (b) Inappropriate therapy: The patient may receive incorrect therapy if the device does not monitor the patient's breathing frequency accurately and reliably. The General and Plastic Surgery Device Classification Panel identified no hazards from this device.

Proposed Classification

FDA agrees with the Panels' recommendations and is proposing that breathing frequency monitors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2375, to read as follows:

§ 868.2375 Breathing frequency monitor.

(a) *Identification.* A breathing (ventilatory) frequency monitor is a device used to measure a patient's respiratory rate. The device provides an audible or visible alarm when the respiratory rate is outside predetermined limits.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33383 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1699]

Medical Devices; Classification of Lung Water Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lung water monitors into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application would include premarket approval information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lung water monitors:

1. Identification: A lung water monitor is a device used to monitor the trend of fluid volume changes in a patient's lung by measuring changes in thoracic electrical impedance (resistance to alternating current) by means of electrodes placed on the patient's chest.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that lung water monitors be classified into class III because the Panel believes that the device presents a potential unreasonable risk of illness or injury. The Panel believes that insufficient information exists to determine whether general controls or performance standards would be adequate to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device, and the lack of clinical data. The Panel notes that there is no acceptable quantitative procedure for measuring changes in lung fluid volume.

5. Risks to health: (a) Incorrect diagnosis: If the device is not calibrated or does not accurately measure changes in lung fluid volume, misdiagnosis of the patient's condition may result in inappropriate therapy. (b) Electrical shock: If the device malfunctions or is not properly grounded, the patient may receive an electrical shock. (c) Allergic reaction: The adhesive backing on the electrodes applied to the chest may cause skin irritation.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that lung water monitors be classified into class III (premarket approval). The agency concurs with the Panel that the device presents potential unreasonable risks of illness or injury to the patient and that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2450, to read as follows:

§ 868.2450 Lung water monitor.

(a) *Identification.* A lung water monitor is a device used to monitor the trend of fluid volume changes in a patient's lung by measuring changes in thoracic electrical impedance (resistance to alternating current) by means of electrodes placed on the patient's chest.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33384 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1700]

Medical Devices; Classification of Cutaneous Oxygen Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cutaneous oxygen monitors into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cutaneous oxygen monitors:

1. Identification: A cutaneous oxygen monitor is a device used to monitor relative changes in the cutaneous (skin) oxygen tension by using a noninvasive sensor (e.g., Clark-type polarographic electrode) placed on the patient's skin.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that cutaneous oxygen monitors be classified into class II because the Panel believes that the design and materials of the device must be controlled to assure that the patient is not burned due to excessive heating of the sensor, that the device accurately measures the cutaneous oxygen tension, that skin injury or allergic reaction does not occur from the use of electrode gels or adhesives, and that the patient does not receive an electrical shock. The Panel believes that the output of the device should be validated by the user against arterial blood-oxygen tension, both initially and with any subsequent change in electrode site. The Panel recommends that the manufacturer be required by FDA to specify in the labeling for the device any conditions known to interfere with the oxygen tension measurement. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on testimony and data presented to the Panel. On June 2, 1977 Mr. Lonny Wolgemuth, representing Litton Medical Electronics, addressed the Panel regarding the Litton Oxymonitor, a device for measuring the cutaneous oxygen tension. The presentation addressed the history of development of the device, its operational principles, applications for use of the device, and alternative methods for the measurement of oxygen tension (PO_2).

Dr. Howard Hochberg, representing Roche Medical Electronics, addressed the Panel on January 24, 1978 concerning the Roche cutaneous oxygen monitor. Dr. Hochberg referenced the utility of the device as a trend monitor and the low incidence of burns reported to date. He concluded his presentation by recommending that the device be classified into class III (premarket approval), contending that there is not enough information to develop a performance standard because the technology for the device is still being developed.

The Panel members raised questions during both of the above presentations concerning the safety and effectiveness of the device. The Panel members' concerns centered on (1) the incidence of and extent of skin injury due to the electrode temperature relative to body weight when the device is used on infants, (2) ranges of linearity, and (3) the position of the electrode on the patient.

Based on these presentations and the data available in the medical literature, the Panel members determined that sufficient data exist on which to base a performance standard.

5. Risks to health: (a) Burns: If the sensor temperature is too high or if the position of the electrode on the patient is not changed periodically, the patient may be burned. (b) Inappropriate therapy: If the device does not measure the patient's oxygen tension accurately, the patient may receive inappropriate therapy. (c) Skin reaction: The electrolyte or adhesive used with the sensor may cause an adverse skin reaction. (d) Electrical shock: If the device is not designed properly, the patient may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cutaneous oxygen monitors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device.

FDA originally placed the cutaneous oxygen monitor into class III (premarket approval) based on premarket notifications made to the agency under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807). FDA was not aware at that time that a substantially equivalent product had been in commercial distribution prior to the date of enactment of the Medical Device Amendment (May 28, 1976). Subsequently, an application for premarket approval and a petition for reclassification were submitted to FDA. Also, new information was presented to FDA showing that the cutaneous oxygen monitor had been in commercial distribution before May 28, 1976. Accordingly, FDA, notified the manufacturers whose submissions on this device were pending that the device was substantially equivalent to a device in commercial distribution prior to enactment of the Medical Device Amendments of 1976 and, therefore, could be marketed without premarket approval or approval of a reclassification petition. The pending submissions were withdrawn by the manufacturers and the cutaneous oxygen monitor was referred to the Anesthesiology Device Classification Panel for a classification recommendation.

During the Panel discussions, differing opinions were expressed about the classification of cutaneous oxygen monitors because the device uses a relatively new technique for measuring oxygen tension. The device uses an external cutaneous electrode to heat the patient's skin and underlying tissues to temperatures greater than 43° C to enable oxygen tension to be measured. Questions were expressed during the Panel's deliberations as to whether there was enough information available to develop a performance standard that would assure the safety and effectiveness of the device. Although the agency tentatively agrees with the Panel and proposes to classify the cutaneous oxygen monitor into class II (performance standards), comments are requested on whether there is sufficient information available to establish a performance standard that will assure the safety and effectiveness of the device without requiring that it undergo premarket clearance by FDA.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2500 as follows:

§ 868.2500 Cutaneous oxygen monitor.

(a) *Identification.* A cutaneous oxygen monitor is a device used to monitor relative changes in the cutaneous (skin) oxygen tension by using a noninvasive sensor (e.g., Clark-type polarographic electrode) placed on the patient's skin.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above offices between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33385 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1702]

Medical Devices; Classification of Pneumotachometers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pneumotachometers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of pneumotachometers:

1. Identification: A pneumotachometer is a device used to determine gas flow by measuring the pressure differential across a known resistance. The device may use a set of capillaries or a metal screen for the resistive element.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that pneumotachometers be classified into class II because the Panel believes the accuracy of the device must be adequate to assure that the device does not generate incorrect data. In addition, the Panel believes that the design and materials of the device must be controlled to assure that when used in a breathing circuit or mechanical ventilator, the device does not increase air-flow resistance excessively or promote infection due to an inability of the user to clean and sterilize the device. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inappropriate therapy: Inaccurate determination of gas flow may cause the patient's condition to be incorrectly diagnosed, resulting in incorrect therapy. (b) High flow resistance: If the device is used in a breathing circuit, poor design may cause excessive flow resistance that could result in inadequate ventilation of the patient. (c) Infection: If the device is not clean or sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that pneumotachometers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2550, to read as follows:

§ 868.2550 Pneumotachometer.

(a) *Identification.* A pneumotachometer is a device used to determine gas flow by measuring the pressure differential across a known resistance. The device may use a set of capillaries or a metal screen for the resistive element.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33386 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1703]

Medical Devices; Classification of Airway Pressure Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying airway pressure monitors into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposed elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesioloogy Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of airway pressure monitors:

1. Identification: An airway pressure monitor is a device used to measure the pressure in a patient's upper airway. The device may include a pressure gauge and an alarm.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that airway pressure monitors be classified into class II because the Panel believes that the device must accurately measure a patient's airway pressure, and changes in that pressure, so that hospital personnel will be alerted to abnormal conditions. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel noted that a standard for pressure gauges is being developed by the American National Standards Institute.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, airway pressure monitors.

5. Risks to health: Inadequate ventilation: Failure of the device to accurately measure airway pressure and pressure changes may result in inadequate ventilation or other inappropriate patient therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that airway pressure monitors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2600, to read as follows:

§ 868.2600 Airway pressure monitor.

(a) *Identification.* An airway pressure monitor is a device used to measure the pressure in a patient's upper airway. The device may include a pressure gauge and an alarm.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33387 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1704]

Medical Devices; Classification of Gas Pressure Gauges

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas pressure gauges into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980.

FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas pressure gauges:

1. Identification: A gas pressure gauge (e.g., bourdon tube pressure gauge) is a device used to measure the gas pressure in a gas delivery system.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas pressure gauges be classified into class II because the Panel believes that the device must be accurate to asssure proper gas delivery pressures. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel noted that standards for this device have been developed by committees of the Compressed Gas Association and the British Standards Institution.

4. Summary of data on which the recommendation is based: The Panel based it recommendation on the Panel members' personal knowledge of, and clinical experience with, gas pressure gauges. There has been extensive clinical experience and widespread use of these devices for many years.

5. Risks to health: Inappropriate therapy: An inaccurate pressure guage may lead to improper functioning of respiratory equipment and resulting inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas pressure gauges be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2610, to read as follows:

§ 868.2610 Gas pressure gauge.

(a) *Identification.* A gas pressure gauge (e.g., Bourdon tube pressure gauge) is a device used to measure gas pressure in a gas delivery system.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33388 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1705]

Medical Devices; Classification of Gas Pressure Calibrators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas pressure calibrators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas pressure calibrators:

1. Identification: A gas pressure calibrator is a device used to calibrate pressure-measuring instruments by generating a known gas pressure.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the gas pressure calibrators be classified into class II to assure that the gas pressure generated by this device is accurate so that the device can be used to calibrate correctly instruments used in the care and treatment of patients. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel noted that standards are being developed by the

Compressed Gas Association (CGA) and the American National Standards Institute (ANSI).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, gas pressure calibrators.

5. Risks to health: Inappropriate therapy: Inaccurate calibration of gas pressure gauges may lead to improper operation of various medical devices used in the support and care of the patient, and the patient may receive incorrect therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas pressure calibrators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2620, to read as follows:

§ 868.2620 Gas pressure calibrator.

(a) *Identification.* A gas pressure calibrator is a device used to calibrate pressure-measuring instruments by generating a known gas pressure.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33389 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1706]

Medical Devices; Classification of Pressure Regulators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pressure regulators into class II (performance standards). FDA is also publishing the recommendations of the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of pressure regulators:

1. Identification: A pressure regulator is a device, often called a pressure-reducing valve, that is used to convert a gas pressure from a high variable pressure to a lower, more constant working pressure. This device includes mechanical oxygen regulators.

2. Recommended classification: Class II (performance standards). Both the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that this device be classified into class II. The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a low priority. The General Hospital and Personal Use Device Classification Panel recommends that establishing a performance standard be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that pressure regulators be classified into class II because the Panels believe the design and materials of the device must be controlled to assure that the device delivers a reliable constant pressure, to assure that the diaphragm has adequate strength to prevent rupture, to assure that the device uses standard fittings, and to assure that the device can be cleaned and sterilized to prevent infection. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: Both Panels based their recommendation on their Panel members' personal knowledge of, and clinical experience with, the device, and widespread use of the device during the past 30 years. The Anesthesiology Device Classification Panel also noted that portions of standards for anesthesia and respiratory equipment developed by the National Fire Protection Association, the Compressed Gas Association, the Interstate Commerce Commission (Department of Transportation), and the Underwriters Laboratories apply to gas pressure regulators.

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risks to health: (a) Overpressurization: Rupture of the regulator diaphragm could allow high gas pressure to be introduced into the patient's airway, possibly resulting in

rupture of a lung. (b) Inappropriate therapy: If the pressure regulator does not supply gas at the correct pressure to the devices supporting the patient, the patient may receive incorrect therapy. (c) Leaks: If the pressure regulator does not have standard fittings, leaks may develop, resuting in an inadequate delivery of gases. (d) Infection: If the regulator is not adequately cleaned or sterilized, contamination of equipment and cross-infection between patients may occur.

The General Hospital and Personal Use Device Classification Panel identified the following risks to health for mechanical oxygen regulators: (a) Hypoxia/hyperoxia: If the regulator does not provide accurate gas pressure or flow the patient may receive too little or too much oxygen. (b) Contamination: If the device is not supplied with proper cleaning instructions, contaminants may be added to the gas stream going to the patient. (c) Leaks: The regulator fittings should be compatible with appropriate gas sources to prevent leaks.

Proposed Classification

FDA agrees with the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommendation and is proposing that pressure regulators be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessay to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2700, to read as follows:

§868.2700 Pressure regulator.

(a) *Identification.* A pressure regulator is a device, often called a pressure-reducing valve, that is used to convert a gas pressure from a high variable pressure to a lower, more constant working pressure. This device includes mechanical oxygen regulators.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33390 Filed 11–1–79 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1707]

Medical Devices; Classification of Electrical Peripheral Nerve Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electrical peripheral nerve stimulators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of electrical peripheral nerve stimulators:

1. Identification: An electrical peripheral nerve stimulator (neuromuscular blockade monitor) is a device used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that electrical peripheral nerve stimulators be classified into class II because the Panel believes that the electrical current may cause burns or electrical shock to the body if the output parameters are not controlled. The Panel believes that the device is safe when used with well-established output parameters. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, electrical peripheral nerve stimulators used in anesthesia.

5. Risks to health: (a) Electrical shock: If the device is not designed properly, the patient or operator may receive an electrical shock. (b) Local burns: Improper electrode surface area or excessive current density can cause burns to the patient's body. (c) Excessive muscle contractions: Improper output parameters can cause excessive muscle contractions in the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that

electrical peripheral nerve stimulators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2775, to read as follows:

§ 868.2775 Electrical peripheral nerve stimulator.

(a) *Identification.* An electrical peripheral nerve stimulator (neuromuscular blockade monitor) is a device used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33391 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1708]

Medical Devices; Classification of Differential Pressure Transducers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying differential pressure transducers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of differential pressure transducers:

1. Identification: A differential pressure transducer is a two-chambered device often used during pulmonary function testing. It generates an electrical signal for subsequent display or processing that is proportional to the difference in gas pressures in the two chambers.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that differential pressure transducers be classified into class II because the Panel believes that the device should produce a signal that accurately reflects the pressure differential between the two chambers. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. These devices have been widely used for many years.

5. Risks to health: Inappropriate therapy: If the device does not accurately measure the difference in pressures, a patient's condition may be incorrectly diagnosed, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that differential pressure transducers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2875, to read as follows:

§ 868.2875 Differential pressure transducer.

(a) *Identification.* A differential pressure transducer is a two-chambered device often used during pulmonary function testing. It generates an electrical signal for subsequent display or processing that is proportional to the difference in gas pressures in the two chambers.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing

Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33392 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1709]

Medical Devices; Classification of Gas Flow Transducers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas flow transducers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas flow transducers:

1. Identification: A gas flow transducers is a device used to convert gas flow rate into an electrical signal for subsequent display or processing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas flow transducers be classified into class II because the Panel believes that the device must generate electrical signals that accurately reflect the gas flow being detected. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel noted the development of standards for this device by committees of the American National Standards Institute and the National Fire Protection Association.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: If the device does not accurately show gas flow rate for display and evaluation by the physician, the patient may receive incorrect treatment.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas flow transducers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2885, to read as follows:

§ 868.2885 Gas flow transducer.

(a) *Identification.* A gas flow transducer is a device used to convert gas flow rate into an electrical signal for subsequent display or processing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33393 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1710]

Medical Devices; Classification of Gas Pressure Transducers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas pressure transducers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas pressure transducers:

1. Identification: A gas pressure transducer is a device used to convert gas pressure into an electrical signal for subsequent display or processing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas pressure transducers be classified into class II because the Panel believes that the device must generate electrical signals that accurately describe the gas pressure being detected. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: If the device does not accurately show pressure signals for display and evaluation by the user, the patient may receive incorrect treatment.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas pressure transducers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2900, to read as follows:

§ 868.2900 Gas pressure transducer.

(a) *Identification.* A gas pressure transducer is a device used to convert gas pressure into an electrical signal for subsequent display or processing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33394 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1714]

Medical Devices; Classification of Emergency Airway Needles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying emergency airway needles into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of emergency airway needles:

1. Identification: An emergency airway needle is a device used to puncture the cricothyroid membrane to provide an emergency airway during upper airway obstruction.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that emergency airway needles be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to minimize the risk of hemorrhage when the device is inserted. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, emergency airway needles.

5. Risks to health: Hemorrhage (bleeding): If the device is of an inappropriate size, shape, or length, hemorrhaging may occur when it is inserted through the cricothyroid membrane.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the emergency airway needles be classified into class II. Although the device is life supporting, the agency believes that premarket approval is unnecessary because this is a simple device with which there has been significant experience and because no reported problems attributed to the device would be diminished by subjecting the device to premarket approval. The agency believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5090, to read as follows:

§ 868.5090 Emergency airway needle.

(a) *Identification.* An emergency airway needle is a device used to puncture the cricothyroid membrane to provide an emergency airway during upper airway obstruction.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33385 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N–1715]

Medical Devices; Classification of Nasopharyngeal Airways

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nasopharyngeal airways into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nasopharyngeal airways:

1. Identification: A nasopharyngeal airway is a device used to facilitate breathing by means of a tube inserted into the patient's pharynx through the nose to provide a patent airway.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the nasopharyngeal airway be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device should be controlled to assure that the device does not promote infection or obstruct or damage the patient's airway. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this deviced is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, nasopharyngeal airways.

5. Risks to health: (a) Epistaxis (nosebleed), obstruction, and tissue damage: If the airway is not shaped properly or is too large or too rigid, it may obstruct the air passage, damage the tissue within the nose, or cause epistaxis.

(b) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the nasopharyngeal airways be classified into class II (performance standards). Although the device is life supporting, the agency believes that class III (premarket approval) is unnecessary for this device because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device, nasopharyngeal airway, using the principles applicable to the standards for the oropharyngeal airway and the tracheal tube, which are similar to the nasopharyngeal airway and which are the subjects of proposed classification regulations published elsewhere in this issue of the **Federal Register.** The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F

by adding new § 868.5100, to read as follows:

§ 868.5100 Nasopharyngeal airway.

(a) *Identification.* A nasopharyngeal airway is a device used to facilitate breathing by means of a tube inserted into the patient's pharynx through the nose to provide a patent airway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33396 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1716]

Medical Devices; Classification of Oropharyngeal Airways

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oropharyngeal airways into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of oropharyngeal airways:

1. Identification: An oropharyngeal airway is a device inserted into the pharynx through the mouth to provide a patent airway.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that oropharyngeal airways be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the device has a proper anatomical shape and sufficient strength and hardness to prevent damage to soft tissue and teeth, and breakage of the device. The Panel believes that general controls alone will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The Panel members noted the widespread use of these devices during the past 25 years by both professional and lay personnel. The use of oropharyngeal airways in emergency resuscitation has been taught to lay personnel through the American Red Cross, the Boy Scouts of America, and various volunteer rescue groups. The American National Standards Institute's Z–79 Committee has written a standard (Z–79.3) addressing the physical characteristics of oropharyngeal airways. (Ref. 1)

5. Risks to health: (a) Soft tissue trauma: Damage to the tissues of the mouth may result from improper insertion or improper anatomical shape of the device. (b) Trauma to teeth: If the airway device is too hard, it may damage the teeth.

(c) Inadequate ventilation: If the airway device is composed of a material that is too soft, it could be blocked or broken by the patient's teeth, rendering the device ineffective.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the oropharyngeal airways be classified into class II. Although the device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. American National Standards Institute, American National Standard for Oropharyngeal Airways, Z–79.3, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 868.5110, to read as follows:

§ 868.5110 Oropharyngeal airway.

(a) *Identification.* An oropharyngeal airway is a device inserted into the pharynx through the mouth to provide a patent airway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket

number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33397 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1717]

Medical Devices; Classification of Anesthesia Conduction Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthesia conduction catheters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthesia conduction catheters:

1. Identification: An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics to provide continuous regional anesthesia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that anesthesia conduction catheters be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure adequate mechanical strength to prevent breakage of the catheter when it is removed from the patient. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. Anesthesia conduction catheters have been widely used for over 33 years.

5. Risks to health: (a) Thromboembolic complications: If the catheter is not strong enough, it may break during extraction from the patient and cause complications such as embolism or thrombus (blood clot) formation. (b) Adverse tissue reaction: If the materials in the catheter are not biocompatible, adverse tissue reaction may occur due to leaching of chemicals from the device.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anesthesia conduction catheters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5120, to read as follows:

§ 868.5120 Anesthesia conduction catheter.

(a) *Identification.* An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics to provide continuous regional anesthesia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33398 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1718]

Medical Devices; Classification of Anesthesia Conduction Filters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthesia conduction filters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthesia conduction filters:

1. Identification: An anesthesia conduction filter is a microporous filter used while administering injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that anesthesia conduction filters be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure both that the filter mesh size adequately prevents foreign bodies from entering a patient, and that the materials used in the filter are biocompatible. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, anesthesia conduction filters.

5. Risks to health: (a) Foreign body reaction: An excessively large mesh size may allow larger particulate matter to enter the patient and cause foreign body reactions. (b) Adverse tissue reaction: If the filter material is not biocompatible, or if toxic substances leach from the filter, an adverse tissue reaction may occur in the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anesthesia conduction filters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5130, to read as follows:

§ 868.5130 Anesthesia conduction filter.

(a) *Identification.* An anesthesia conduction filter is a microporous filter used while administering injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33399 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1719]

Medical Devices; Classification of Anesthesia Conduction Kits

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthesia conduction kits into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthesia conduction kits:

1. Identification: An anesthesia conduction kit is a device used to administer conduction anesthesia. The device may contain syringes, needles, and drugs.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that anesthesia conduction kits be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the strength of

the needles or catheters is adequate to prevent breakage and to assure that the components and anesthetic agents can be adequately cleaned and sterilized to prevent sepsis (infection), particulate contamination of the spinal fluid, and chemical contamination. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted that a committee of the Association for the Advancement of Medical Instrumentation (AAMI) is developing needle standards.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Trauma: If the needles or catheters break during the procedure, trauma to the patient may result. (b) Sepsis (infection) and particulate contamination: If the device is not clean and sterile, sepsis or particulate contamination of the spinal fluid may result. (c) Adverse tissue reaction: Chemical contamination of the local anesthetic agent may cause adverse tissue reactions in the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anesthesia conduction kits be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5140, to read as follows:

§ 868.5140 Anesthesia conduction kit.

(a) *Identification.* An anethesia conduction kit is a device used to administer conduction anesthesia. The device may contain syringes, needles, and drugs.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33400 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1720]

Medical Devices; Classification of Anesthesia Conduction Needles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthesia conduction needles into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthesia conduction needles:

1. Identification: An anesthesia conduction needle is a device used to inject local anesthetics into a patient to provide regional anesthesia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the anesthesia conduction needles be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the device is strong enough to prevent breakage, that the needle and needle tip are properly shaped to prevent damage to blood vessels, and that the hub is designed to prevent leakage when changing needles on a syringe. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, anesthesia conduction needles.

5. Risks to health: (a) Blood vessel damage or thrombus (blood clot): Improper needle or needle-tip shape or strength may cause thrombus formation or vessel damage. (b) Leakage: Leakage of anesthetics may occur when changing needles on a syringe if the hub is not properly designed. (c) Breakage: If the needle breaks while in the patient, complications may ensue.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anesthesia conduction needles be classified into class II (performance standards). The agency believes that a

performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5150, to read as follows:

§ 868.5150 Anesthesia conduction needle.

(a) *Identification.* An anesthesia conduction needle is a device used to inject local anesthetics into a patient to provide regional anesthesia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33401 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1721]

Medical Devices; Classification of Anesthesia Gas Machines

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthesia gas machines into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the Dental Device Classification Panel, an FDA advisory committees, made the following recommendation regarding the classification of anesthesia gas machines:

1. Identification: An anesthesia gas machine is a device used to administer, continuously or intermittently, a general inhalation anesthetic or analgesic agent to a patient and to maintain a patient's ventilation. The device may include a gas flowmeter, vaporizer, ventilator, breathing circuit with bag, and emergency gas supply.

2. Recommended classification: Class II (performance standards). Both the Anesthesiology Device Classification Panel and Dental Device Classification Panel recommend that this device be classified into class II (performance standards). The Anesthesiology Device Classification Panel recommends that establishing a performance standard be a high priority. The Dental Device Classification Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Anesthesiology Device Classification Panel and the Dental Device Classification Panel recommend that the anesthesia gas machine be classified into class II (performance standards) because the Panels believe that the design of the device must be controlled to assure that the patient is properly anesthetized and ventilated. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which recommendation is based: The Anesthesiology Device Classification Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. The Anesthesiology Panel also noted the widespread use of this device during the past 50 years and the development of a standard for continuous flow anesthesia machines by the Z–79 Committee of the American National Standards Institute (Ref. 1). The Dental Device Classification Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and the potential hazards to the patient associated with the use of the device.

5. Risks to health: The Anesthesiology Device Classification Panel noted the following risks to health: (a) Inappropriate therapy: Incorrect calibration of the device may lead to delivery of an incorrect gas mixture to the patient. (b) Inappropriate dosage: Poor design or malfunction could result in leaks in the system that cause the patient to receive less than the appropriate gas volume. (c) Injury: Fire and explosion from flammable or explosive anesthetic agents may result in severe injury to the patient. (d) Inadequate ventilation: Mechanical failure causing obstruction of the air pathway may result in the patient receiving inadequate ventilation. (e) Overdistension of lung tissue: Mechanical failure resulting in overpressurization of the patient's pulmonary system may lead to overdistension of lung tissue (pneumothorax). The Dental Device Classification Panel identified the following additional risk to health: (f) Brain damage, cardiac arrest, or death: Mechanical failure of the device's valves and flowmeters may cause brain damage, cardiac arrest, or death.

Proposed Classification

FDA agrees with the Panel and is proposing that anesthesia gas machines be classified into class II (performance standards). Although the device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that general controls alone are insufficient to control the risks to health presented by the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Proposed Minimum Performance and Safety Requirements for Components and Systems of Continuous Flow Anesthesia Machines," American National Standards Institute, Z–79.8, draft, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5160 to read as follows:

§ 868.5160 Anesthesia gas machine.

(a) *Identification.* An anesthesia gas machine is a device used to continuously or intermittently administer a general inhalation anesthetic or analgesic agent to a patient and to maintain a patient's ventilation. The device may include a gas flowmeter, vaporizer, ventilator, breathing circuit with bag, and emergency gas supply.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA—305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs

[FR Doc. 79–33402 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1722]

Medical Devices; Classification of Laryngotracheal Topical Anesthesia Applicators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying laryngotracheal topical anesthesia applicators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of laryngotracheal topical anesthesia applicators:

1. Identification: A laryngotracheal topical anesthesia applicator is a device used to apply topical anesthetics to a patient's laryngotracheal area.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that laryngotracheal topical anesthesia applicators be classified into class II (performance standards) because the Panel believes that the design and construction of, and the materials used in, the device must be adequate to assure that all of the components are secure, to prevent the patient from aspirating disconnected device components. In addition, the device should be both sterile and of the proper size and shape to avoid causing trauma to the patient's airway. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, topical anesthesia applicators and related devices.

5. Risks to health: (a) Aspiration of components: Disconnection of the components may result in accidental aspiration of components. (b) Trauma: Improper size, shape, or rigidity of the device may cause trauma to the patient's airway upon insertion. (c) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that laryngotracheal topical anesthesia applicators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C 360c, 371(a))) and under authority

delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5170, to read as follows:

§ 868.5170 Laryngotracheal topical anesthesia applicator.

(a) *Identification.* A laryngotracheal topical anesthesia applicator is a device used to apply topical anesthetics to a patient's laryngotracheal area.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33403 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1723]

Medical Devices; Classification of Rocking Beds

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rocking beds into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rocking beds:

1. Identification: A rocking bed is a device used to temporarily help patient ventilation (breathing) by repeatedly tilting the patient, thereby using the weight of the abdominal contents to move the diaphragm.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that rocking beds be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the patient is properly supported and restrained to prevent injury from falling. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is unnecessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, rocking beds.

5. Risks to health: Injury: The patient may fall out of the bed and be injured.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rocking beds be classified into class II (performance standards). Although the device is life supporting, the agency believes that premarket approval is unnecessary because there has been significant experience with the device and because no reported problems attributed to the device would be diminished by subjecting the device to premarket approval. The agency believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5180, to read as follows:

§ 868.5180 Rocking bed.

(a) *Identification.* A rocking bed is a device used to temporarily help patient ventilation (breathing) by repeatedly tilting the patient, thereby using the weight of the abdominal contents to move the diaphragm.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33404 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1726]

Medical Devices; Classification of Blow Bottles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for

public comment a proposed regulation classifying blow bottles into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of blow bottles:

1. Identification: A blow bottle is a device used to induce a forced expiration from a patient. The patient blows into the device to move a column of water from one bottle to another.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that blow bottles be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device presents no risks to health, and the integrity of the device can be easily determined by examining it. Therefore, the Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that blow bottles be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a blow bottle be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device who does not label or otherwise represent it as sterile be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records and reports, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a blow bottle, even when it is not labeled or otherwise represented as sterile, must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a blow bottle must still be required to comply with the general requirements concerning records and reports in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. A manufacturer of a blow bottle that is labeled or otherwise represented as sterile is, in the manufacture of this device, subject to the GMP regulation in its entirety.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5220, to read as follows:

§ 868.5220 Blow bottle.

(a) *Identification.* A blow bottle is a device used to induce a forced expiration from a patient. The patient blows into the device to move a column of water from one bottle to another.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33405 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1727]

Medical Devices; Classification of Anesthesia Breathing Circuits

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthesia breathing circuits into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final

regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthesia breathing circuits:

1. Identification: An anesthesia breathing circuit is a device used to administer medical gases to a patient during anesthesia. It provides both an inhalation and exhalation route and may include a connector, adaptor, and Y-piece.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that anesthesia breathing circuits be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure leak-free connections and components, to prevent inadequate ventilation, to prevent fire hazards, and to assure low resistance to gas flow in the breathing circuit. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is unnecessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, breathing circuits. Breathing circuits have been used for the past 35 years. They are well accepted by the medical community worldwide, and their performance characteristics are clearly understood.

5. Risks to health: (a) Failure to deliver gas: If the breathing circuit becomes obstructed or disconnected, gas delivery to the patient may be reduced, leading to hypoxia (lack of oxygen) or insufficient anesthesia. (b) Increased breathing effort: If the circuit exhibits excessive resistance to gas flow or if excessive pressures develop within the circuit, the patient may have difficulty breathing. (c) Burns: If the circuit leaks flammable gases, fire, and explosion may result.

Proposed Classification

FDA agrees with the Panel recommendation and proposes that anesthesia breathing circuits be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5240, to read as follows:

§ 868.5240 Anesthesia breathing unit.

(a) *Identification.* An anesthesia breathing circuit is a device used to administer medical gases to a patient during anesthesia. It provides both an inhalation and exhalation route and may include a connector, adaptor, and Y-piece.

(b) *Classification.* Class II (performance standards). Interested persons, may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m. Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33406 Filed 11–01–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1728]

Medical Devices; Classification of Breathing Circuit Circulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breathing circuit circulators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device by classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory

committee, made the following recommendation regarding the classification of breathing circuit circulators:

1. Identification: A breathing circuit circulator is a turbine device attached to a closed breathing circuit. The device is used to circulate anesthetic gases continuously by maintaining the unidirectional valves in an open position and reducing mechanical dead space and resistance in the breathing circuit.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that breathing circuit circulators be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that the device is installed correctly and provides adequate circulation to prevent rebreathing, and that any gas turbulence produced by the device does not cause excessive flow resistance. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device and related devices.

5. Risks to health:

(a) Impeded breathing: Reverse attachment of the circulator device to the breathing circuit may cause closure of breathing circuit valves, impeding the patient's breathing.

(b) Difficulty in breathing: Excessive flow resistance due to turbulence or inadequate circulation may cause difficulty in breathing.

(c) Rebreathing: Inadequate circulation may result in rebreathing of exhaled gases.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that breathing circuit circulators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5250, to read as follows:

§ 868.5250 Breathing circuit circulator.

(a) *Identification.* A breathing circuit circulator is a turbine device attached to a closed breathing circuit. The device is used to circulate anesthetic gases continuously by maintaining the unidirectional valves in an open position and reducing mechanical dead space and resistance in the breathing circuit.

(b) *Classification.* Class II (performance standards). Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33407 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1729]

Medical Devices; Classification of Breathing Circuit Bacterial Filters

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breathing circuit bacterial filters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of breathing circuit bacterial filters:

1. Identification: A breathing circuit bacterial filter is a device used to remove microbiological and particulate matter from the gases in the breathing circuit.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that breathing circuit bacterial filters be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the filter does not add excessive flow resistance or promote bacterial contamination of the breathing circuit. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel

members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Increased breathing resistance: Absorption of water by the filter may impede gas flow in the breathing circuit thereby requiring increased patient effort. (b) Bacterial contamination: A reversal of airflow through the filter may cause bacterial contamination of the gases in the breathing circuit.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that breathing circuit bacterial filters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5260, to read as follows:

§ 868.5260 Breathing circuit bacterial filter.

(a) *Identification.* A breathing circuit bacterial filter is a device used to remove microbiological and particulate matter from the gases in the breathing circuit.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33406 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N–1730]

Medical Devices; Classification of Breathing System Heaters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breathing system heaters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of breathing system heaters:

1. Identification: A breathing system heater is a device used to warm respiratory gases before they enter the patient's airway. The device may include a temperature controller.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that breathing system heaters be classified into class II (performance standards) because the Panel believes that the heat output of this important and widely used device must be such that the gases are heated to a proper temperature. Overheating can cause hyperthermia and thermal burns, and inadequate heating can cause hypothermia. Improper heating may be caused by an inadequate heat controller or improper heat output where there is no controller. The electrical design must be adequate to assure that the patient or operator does not receive an electrical shock. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based it recommendation on the Panel members' personal knowledge of, and clinical experience with, breathing system heaters. The Panel noted that appropriate sections of electrical safety standards may apply.

5. Risks to health: (a) Hyperthermia and burns: If the breathing gases are overheated because of inadequate controls or excessive heat output, burns or hyperthermia may result. (b) Hypothermia: If the gases are underheated as a result of inadequate controls or insufficient heat output, hypothermia may result. (c) Electrical shock: If the device is not designed properly the patient or operator may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that breathing system heaters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F

by adding new § 868.5270, to read as follows:

§ 868.5270 Breathing system heater.

(a) *Identification.* A breathing system heater is a device used to warm respiratory gases before they enter a patient's airway. The device may include a temperature controller.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33409 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1731]

Medical Devices; Classification of Breathing Tube Supports

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breathing tube supports into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James. R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of breathing tube supports:

1. Identification: A breathing tube support is a device used to support and anchor a patient's breathing tube(s).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that breathing tube supports be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that when the device is used in an explosive atmosphere, an explosion does not occur from the build-up of static electrical charges due to the use of nonconductive materials or improper grounding. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted that standards or sections of the standards developed by the Association of Operating Room Nurses (AORN) and the National Fire Protection Association (NFPA) may apply to this device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, breathing tube supports. There has been widespread use of these devices for many years.

5. Risks to health: Explosion: If the device is used in the presence of flammable gases, the build-up of static electricity from the use of nonconductive materials and/or improper grounding may result in an explosion.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that breathing tube supports be classified into class I (general controls) with no exemptions. Because users are familiar with these simple devices and have used them successfully for many years without significant problems, the agency believes that a performance standard is unnecessary. The agency believes that general controls, including appropriate labeling regarding the conductivity or nonconductivity of the device and warnings against use of the nonconductive device in the presence of flammable anesthetic agents, are sufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 710(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5280, to read as follows:

§ 868.5280 Breathing tube support.

(a) *Identification.* A breathing tube support is a device used to support and anchor a patient's breathing tube(s).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs

[FR Doc. 79–33410 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N-1732]

Medical Devices; Classification of Carbon Dioxide Absorbents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carbon dioxide absorbents into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of carbon dioxide absorbents:

1. Identification: Carbon dioxide absorbent is a device consisting of an absorbent material (e.g., soda lime) used to remove carbon dioxide from the gases in a breathing circuit.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that carbon dioxide absorbents be classified into class II (performance standards) because the Panel believes that the properties of this device must be controlled to assure that the device has an adequate carbon dioxide absorbing capacity to prevent hypercapnia (excess carbon dioxide in the blood) of the patient, to assure that dust caused by excessive flakiness is not introduced into the airway, and to assure that excessive resistance to gas flow does not result in inadequate ventilation.

The Panel believes that general controls will not provide sufficient control over these characteristics. Although the Panel believes that this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, carbon dioxide absorbents. Carbon dioxide absorbent material is listed in the United States Pharmacopeia (U.S.P.).

5. Risks to health: (a) Hypercapnia (excess carbon dioxide in the blood): If the device lacks sufficient absortion capacity, patient hypercapnia could result. (b) Inadequate ventilation: If the carbon dioxide absorbent adds excessive resistance to the breathing circuit, the patient may be inadequately ventilated. (c) Cross infection: If the device cannot be disinfected, a patient using the device may contract an infection after its use by another patient. (d) Airway irritation: If the carbon dioxide absorbent material is excessively flaky, particles or dust may be introduced into the patient's airway, possibly causing irritation of the patient's airway.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that carbon dioxide absorbents be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because this is a simple device with which there has been significant experience and because no reported problems attributed to the device would be diminished by subjecting the device to premarket approval. The agency believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5300, to read as follows:

§ 868.5300 Carbon dioxide absorbent.

(a) *Identification.* Carbon dioxide absorbent is a device consisting of an absorbent material (e.g., soda lime) used to remove carbon dioxide from the gases in the breathing circuit.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33411 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1733]

Medical Devices; Classification of Carbon Dioxide Absorbers

AGENCY: Food and Drug Administration

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carbon dioxide absorbers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The

effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of carbon dioxide absorbers:

1. Identification: A carbon dioxide absorber is a device used in a breathing circuit as a container for carbon dioxide absorbent. It may include a canister and water drain.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standards for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the carbon dioxide absorber be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to assure that the absorber does not leak, causing inadequate carbon dioxide removal, and that dust or other irritants are not delivered to the patient. The Panel believes that general controls will not provide sufficient control over these characterisics. Although the Panel believes that this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficent information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device and the widespread use of the device during the past 25 years.

5. Risks to health: (a) Airway irritation: If the absorber allows dust to enter the breathing system, the dust could cause an allergic reaction and irritation of the patient's airway. (b) Inadequate carbon dioxide removal: Gas leakage in the absorber could result in an inadequate removal of carbon dioxide from the exhaled gas, possibly causing hypercapnia (excess carbon dioxide in the blood).

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that carbon dioxide absorbers be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecesaary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5310, to read as follows:

§ 868.5310 Carbon dioxide absorber.

(a) *Identification.* A carbon dioxide absorber is a device used in a breathing circuit as a container for carbon dioxide absorbent. It may include a canister and water drain.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980. submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33412 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1734]

Medical Devices; Classification of Reservoir Bags

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying reservoir bags into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federcl Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following

recommendation regarding the classification of reservoir bags:

1. Identification: A reservoir bag is a device, usually made of conductive rubber, used in a breathing circuit as a reservoir for breathing gas and to assist, control, and/or monitor a patient's ventilation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that reservoir bags be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the bag has a leak-free connection with the breathing circuit and proper elasticity to prevent the patient from being inadequately ventilated. The Panel believes that general controls will not provide sufficient control over these characteristics. Although the Panel believes that reservoir bags are life-supporting devices, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the devices because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and its widespread use during the past 25 years. The Panel also cited the American National Standards Institute's Z–79 Committee Standard for Anesthetic Reservoir Bags (Z–79.4, 1974) (Ref. 1) and noted that Underwriters Laboratory (UL) and the National Fire Protection Association (NFPA) standards also may apply to the device.

5. Risks to health: (a) Inadequate ventilation: If the reservoir bag is not properly connected to the other components in the breathing circuit, leaks may develop, resulting in an inadequate delivery of breathing gas to the patient. In addition, if the reservoir bag is not sufficiently elastic, excessive pressure may develop in the breathing circuit, resulting in inadequate ventilation of the patient. (b) Burns, explosion: If the device is used in the presence of flammable gases, the build-up of static electricity from the use of nonconductive materials may result in an explosion.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that reservoir bags be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard to provide reasonable assurance of the safety and effectiveness of this device. The agency also believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. American National Standards Institute, Anesthetic Reservoir Bags, Z–79.4, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5320, to read as follows:

§ 868.5320 Reservoir bag.

(a) *Identification.* A reservoir bag is a device, usually made of conductive rubber, used in a breathing circuit as a reservoir for breathing gas and to assist, control, and/or monitor a patient's ventilation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33413 Filed 11–1–79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N–1735]

Medical Devices; Classification of Breathing Gas Mixers

AGENCY: Food and Drug Administration

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breathing gas mixers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of breathing gas mixers:

1. Identification: A breathing gas mixer is a device used in conjuction with a respiratory support apparatus to

facilitate and control the mixing of gases that are to be breathed by a patient.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that breathing gas mixers be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to assure that the patient receives the correct mixture of gases for breathing. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is unnecessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Incorrect gas mixtures: If the device is designed so that more than one type of gas can be connected to the same fitting, or if the device is not calabrated properly, the patient may breathe an incorrect gas mixture.

Proposed Classification

FDA agrees with the Panel and is proposing that breathing gas mixers be classified into class II (performance standards). Although the device is life supporting, the agency believes that premarket approval is unnecessary because the principles applicable to the mixing of two or more gases are well understood. The agency believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5330, to read as follows:

§ 868.5330 Breathing gas mixer.

(a) *Identification.* A breathing gas mixer is a device used in conjuction with a respiratory support apparatus to facilitate and control the mixing of gases that are to be breathed by a patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33414 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N–1736]

Medical Devices; Classification of Nasal Oxygen Cannulas

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nasal oxygen cannulas into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of nasal oxygen cannulas:

1. Identification: A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through the nose.

2. Recommended classification: Class I (general controls). Both the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that this device be classified into class I (general controls). The Anesthesiology Device Classification Panel recommends that the device be exempted from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)). The General Hospital and Personal Use Device Classification Panel recommends that this device be exempt from the registration regulation under section 510 of the act (21 U.S.C. 360) and from the good manufacturing practice regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panels recommend that the nasal oxygen cannula be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The user can easily determine whether the device is safe and effective by examining it.

4. Summary of data on which the recommendation is based: Both Panels based their recommendation on their Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: The Anesthesiology Device Classification Panel identified no risks to health. The General Hospital and Personal Use Device Classification Panel identified the following risks to health: (a) Infection: If the device is not

sterile, infection may result. (b) Tissue reactions: If the materials used in the device are not biocompatible, they may cause tissue reaction.

Proposed Classification

FDA agrees with the recommendation of both Panels and is proposing that nasal oxygen cannulas be classified into class I (general controls). FDA disagrees with the recommendation of both Panels that manufacturers of nasal oxygen cannulas be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of a nasal oxygen cannula having defects that could harm users.

FDA disagrees with the General Hospital and Personal Use Device Classification Panel recommendation that manufacturers of nasal oxygen cannulas be exempt from the registration regulation under section 510 of the act (21 U.S.C. 360). Under section 510(g)(4), the agency may exempt a manufacturer from section 510 only upon a finding that compliance with this section is not necessary for the protection of the public health. In the case of a nasal oxygen cannula, the agency cannot make the required finding. To protect the public health, the agency needs to require manufacturers of this device to register and to list their products with FDA, so that the agency is able to identify the firms manufacturing this device and to conduct necessary inspections. Premarket notification by these manufacturers assures that FDA learns of new products, and of significant modifications of existing products, for which premarket approval is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5340, to read as follows:

§ 868.5340 Nasal oxygen cannula.

(a) *Identification.* A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through the nose.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33415 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1737]

Medical Devices; Classification of Nasal Oxygen Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nasal oxygen catheters into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nasal oxygen catheters:

1. Identification: A nasal oxygen catheter is a device that is inserted through a patient's nostril to administer oxygen.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that nasal oxygen catheters be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements because any defects in the device are readily detectable.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nasal oxygen catheters be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA disagrees with the Panel's recommendation that manufacturers of nasal oxygen catheters be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of nasal oxygen catheters having defects that could harm users.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21

U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5350, to read as follows:

§ 868.5350 Nasal oxygen catheter.

(a) *Identification.* A nasal oxygen catheter is a device that is inserted through a patient's nostril to administer oxygen.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33416 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1738]

Medical Devices; Classification of Posture Chairs for Cardiac and Pulmonary Treatment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying posture chairs for cardiac and pulmonary treatment into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of posture chairs for cardiac and pulmonary treatment:

1. Identification: A posture chair for cardiac and pulmonary treatment is a device used to assist in the rehabilitation and mobilization of patients with chronic heart and lung disease.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that posture chairs for cardiac and pulmonary treatment be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements because undetected defects in the device would not have an adverse effect on the patient.

4. Summary of data on which the recommendation is based: The Panel based it recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that posture chairs for cardiac and pulmonary treatment be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a posture chair for cardiac and pulmonary treatment be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device, and that any defect in the device that is not readily detectible will not result in a device failure that could have an adverse effect on the patient or other user. The agency believes, however, that manufacturers of a posture chair for cardiac and pulmonary treatment must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a posture chair for cardiac and pulmonary treatment must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5365, to read as follows:

§ 868.5365 Posture chair for cardiac and pulmonary treatment.

(a) *Identification.* A posture chair for cardiac and pulmonary treatment is a device used to assist in the rehabilitation and mobilization of patients with chronic heart and lung disease.

(b) *Classification.* Class I (general controls).

The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198 with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33417 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N–1739]

Medical Devices; Classification of Heat and Moisture Condensers (Artificial Nose)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying heat and moisture condensers (artificial nose) into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of heat and moisture condensers (artificial nose):

1. Identification: A heat and moisture condenser (artificial nose) is a device positioned over a tracheotomy (a surgically created opening in the throat) or tracheal tube (a tube inserted into the trachea) to warm and humidify gases breathed in by a patient.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that heat and moisture condensers be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure low resistance to gas flow, proper dead space (space not utilized for gas exchange with the blood) according to the size of the patient for whom it is designed, standard connector fittings, and proper size and shape to prevent premature obstruction by secretions. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, heat and moisture condensers.

5. Risks to health: (a) Inadequate ventilation (breathing): Inadequate ventilation may be caused by excessive resistance to gas flow, improper dead space, or connectors that do not fit. (b) Obstruction by secretions: Improper size or shape may cause premature obstruction of the tracheotomy by secretions.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that heat and moisture condensers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5375, to read as follows:

§ 868.5375 Heat and moisture condenser (artificial nose).

(a) *Identification.* A heat and moisture condenser (artificial nose) is a device positioned over a tracheotomy (a surgically created opening in the throat) or tracheal tube (a tube inserted into the trachea) to warm and humidify gases breathed in by a patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33418 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1740]

Medical Devices; Classification of Water-Seal Thoracic Drainage Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying water-seal thoracic drainage systems into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of water-seal thoracic drainage systems:

1. Identification: A water-seal thoracic drainage system is a device used to restore subatmospheric intrapleural pressure (pressure in the space between the lungs and the chest wall) and to drain fluid from the pleural space, by means of a chest tube. The device is usually connected to a suction system.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that water-seal thoracic drainage systems be classified into class II (performance standards) because the Panel believes that standards are necessary to assure that the device supplies adequate suction for drainage of the pleural space, and because it believes that the materials used in the device are controlled to assure a good connection between the device and the patient to prevent pneumothorax (accumulation of gas in the pleural space). The Panel believes that general controls would not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, water-seal thoracic drainage systems. In addition, the Panel members are aware that there have been few reported malfunctions or failures of this type of device (e.g., as reported in the FDA Medical Device Experience Monitoring Network files) relative to the number of these devices in use.

5. Risks to health: (a) Failure to establish subatmospheric intrapleural pressure: A loss of suction could reduce the effectiveness of the device in establishing a subatmospheric intrapleural pressure and in providing adequate drainage from the pleural space. (b) Pneumothorax (an accumulation of gas in the pleural space): Disconnection of the device from the patient may cause a pneumothorax, resulting in impaired lung function.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that water-seal thoracic drainage systems be classified into class II. Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5385, to read as follows:

§ 868.5385 Water-seal thoracic drainage system.

(a) *Identification.* A water-seal thoracic drainage system is a device used to restore subatmospheric intrapleural pressure (pressure in the space between the lungs and the chest wall) and to drain fluid from the pleural space, by means of a chest tube. The device is usually connected to a suction system.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 33419 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1741]

Medical Devices; Classification of Electroanesthesia Apparatus

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroanesthesia apparatus into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer

of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the Neurological Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of electroanesthesia apparatus:

1. Identification: An electroanesthesia apparatus is a device used for the induction and maintenance of anesthesia during surgical procedures by means of an alternating or pulsed electric current that is passed through electrodes fixed to the patient's head.

2. Recommended classification: Class III (premarket approval). Both the Anesthesiology Device Classification Panel and the Neurological Device Classification Panel recommend that the electroanesthesia apparatus be classified into class III (premarket approval). Both Panels recommend that premarket approval for this device be a low priority.

3. Summary of reasons for recommendation: Both the Anesthesiology Device Classification Panel and the Neurological Device Classification Panel recommend that electroanesthesia apparatus be classified into class III (premarket approval) because the device presents a potential unreasonable risk of illness or injury to the patient. The Panels believe that there is not sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device, and that there is insufficient information to show that general controls will provide such assurance. Therefore, the device should be subject to premarket approval to ensure that manufacturers satisfactorily demonstrate the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Anesthesiology Device Classification Panel based its recommendation on the insufficient number of domestic studies on human subjects. The Panel has not seen any medical data on which to judge the safety and effectiveness of the device, and believes that the technique of electroanesthesia is not considered a well-established or well-recognized clinical procedure. The Neurological Device Classification Panel noted that many factors important to the clinical application of this technique have not been sufficiently defined. The Neurological Device Classification Panel also based its recommendation on the Panel members' experience with the device, and their judgment and knowledge of the pertinent literature (Ref. 1). The National Research Council recommends that electroanesthesia be considered as a potentially useful adjunct in the maintenance of anesthesia but that electroanesthesia should be limited to investigational use until its effects, advantages, and standardization can be adequately evaluated.

5. Risks to health: (a) Electrical shock: Improper electrical grounding may allow the patient or operator to receive an electrical shock. (b) Damage to central nervous system: Excessively high electrical current or voltage could damage the central nervous system and cerebral tissues. (c) Skin burns: If the electrodes are too small and yield a high current density, skin burns may result. (d) Skin irritation: Electrode gels or pastes used to establish electrical contact between the electrode and the skin may cause skin irritation. (e) Cardiac or pulmonary interference: The position of the electrode on the head may lead to electrical interference with cardiac or pulmonary functions in the patient.

Proposed Classification

FDA agrees with the recommendation of the Anesthesiology Device Classification Panel and the Neurological Device Classification Panel and is proposing that the electroanesthesia apparatus be classified into class III (premarket approval). The agency believes that the safety and effectiveness of the device has not been established and that the device presents a potential unreasonable risk of illness or injury to the patient because of the high electrical currents necessary to induce an anesthetic state in a patient. The agency concurs with both Panels that insufficient information exists on this device either to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or to establish a performance standard to provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "An Evaluation of Electroanesthesia and Electrosleep," National Research Council, NTIS, PB–241–305, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5400, to read as follows:

§ 868.5400 Electroanesthesia apparatus.

(a) *Identification.* An electroanesthesia apparatus is a device used for the induction and maintenance of anesthesia during surgical procedures by means of an alternating or pulsed electric current that is passed through electrodes fixed to the patient's head.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 24, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33420 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1743]

Medical Devices; Classification of Ether Hooks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ether hooks into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ether hooks:

1. Identification: An ether hook is a device that fits inside the patient's mouth and is used to deliver vaporized ether.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempted from good manufacturing practice regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that ether hooks be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards to control the identified risks to health. The Panel believes that defects in the device are readily detectable before use, and, therefore, the Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Tissue damage: Sharp edges on the hook may cause tissue trauma. (b) Overexposure: if the hook is poorly designed, persons in the areas of use may be subjected to excessive environmental ether contamination. (c) Tissue reaction: If the hook materials are not biocompatible, they may cause tissue reactions.

Proposed Classification

FDA agrees with the Panel and is proposing that ether hooks be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of an ether hook be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device who does not label or otherwise represent it as sterile be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of an ether hook, even when it is not labeled or otherwise represented as sterile, must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of an ether hook must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. A manufacturer of an ether hook that is labeled or otherwise represented as sterile is, in the manufacture of this device, subject to the GMP regulation in its entirety.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5420, to read as follows:

§ 868.5420 Ether hook.

(a) *Identification.* An ether hook is a device that fits inside the patient's mouth and is used to deliver vaporized ether.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 24, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33421 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1744]

Medical Devices; Classification of Gas-Scavenging Apparatus

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas-scavenging apparatus into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II.The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James. R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas-scavenging apparatus:

1. Identification: A gas-scavenging apparatus is a device used to collect excess anesthetic, analgesic, and trace gases and vapors from a breathing system, ventilator, or extracorporeal pump-oxygenator, and conduct these gases out of the personnel area by means of an exhaust system.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas-scavenging apparatus be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that it does not cause excessive breathing resistance, which prevents the patient from receiving adequate ventilation. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted that a standard has been proposed by the American National Standards Institute Z-79 committee.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, gas-scavenging apparatus.

5. Risks to health: (a) Inadequate ventilation: Development of excessive negative pressure in the breathing circuit may cause high breathing resistance, resulting in inadequate ventilation of the patient. Excessive resistance or an obstruction in the scavenging system may cause an excessive pressure buildup in the breathing circuit such that the patient cannot exhale.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas-scavenging apparatus be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 710(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5430, to read as follows:

§ 868.5430 Gas-scavenging apparatus.

(a) *Identification.* A gas-scavenging apparatus is a device used to collect excess anesthetic, analgesic, and trace gases and vapors from a-breathing system, ventilator, or extracorporeal pump-oxygenator, and conduct these gases out of the personnel area by means of an exhaust system.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33422 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1745]

Medical Devices; Classification of Portable Oxygen Generators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying portable oxygen generators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation

based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of portable oxygen generators:

1. Identification: A portable oxygen generator is a device that uses either a chemical reaction or physical means (e.g., molecular sieve) to release oxygen for respiratory therapy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that portable oxygen generators be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that oxygen is released in sufficient quantities to support proper ventilation, that the oxygen is pure, and that there are no oxygen leaks into the environment, which increase the risk of fire and burns. The Panel believes that general controls would not provide sufficient control over these characteristics. Although portable oxygen generators are life-supporting devices, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the devices because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Fire and burns: Oxygen leaks into the environment because of faulty device design or construction could result in an explosion or fire, which may cause burns. (b) Infection: The oxygen released may contain contaminants that cause infection or allergic reaction. (c) Inadequate oxygen production: If the device does not produce enough oxygen to meet the patient's demands, hypoxia (lack of oxygen) may result.

Proposed classification

FDA agrees with the Panel and is proposing that portable oxygen generators be classified into class II. Although the device supplies supplemental oxygen that may, in an emergency, be life supporting, the agency believes that premarket approval is unnecessary because the risks to health associated with the device can be controlled by standardization and by following good manufacturing practices. The agency believes that there is sufficient information to establish a performance standard for this device. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5440, to read as follows:

§ 868.5440 Portable oxygen generator.

(a) *Identification.* A portable oxygen generator is a device that uses either a chemical reaction or physical means (e.g., molecular sieve) to release oxygen for respiratory therapy.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33423 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1746]

Medical Devices; Classification of Respiratory Gas Humidifiers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying respiratory gas humidifiers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of respiratory gas humidifiers:

1. Identification: A respiratory gas humidifier is a device used to add moisture to, and sometimes warm, the

breathing gases to the patient. Cascade, gas, heated, and prefilled humidifiers are included in this generic type of device.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendations that respiratory gas humidifiers be classified into class II (performance standards) because the Panel believes that the output of the device must be controlled to assure both adequate humidification of the gases to prevent drying of the patient's airway, and that the gases are properly heated to prevent burns of the upper airway, trachea, and facial areas. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. The Panel also cited the standard currently being developed by the Z–79 Committee of the American National Standards Institute concerning humidifiers and nebulizers.

5. Risks to health: (a) Overhydration: Administration of gases containing a large amount of water may cause a water overload in the patient that could be hazardous, particularly to small infants. (b) Drying of airway: If the device does not properly humidify the inspired gas mixture, the dry gas may cause drying of the patient's airways. (c) Burns, hyperthermia: Excessive heating of the inspired gas mixture by the humidifier may lead to burns in the upper airway, trachea, or facial areas or to hyperthermia (a generalized elevation in body temperature). (d) Infection or allergic reaction: Bacteria and other microorganisms may multiply in the warm, moist environment of the humidifier. Inhalation of these microorganisms by the patient may result in infection or allergic reaction.

Proposed Classification

FDA agrees with the Panel and is proposing that respiratory gas humidifiers be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard for this device. The agency also believes that a performance standard is necessary because general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5450, to read as follows:

§ 868.5450 Respiratory gas humidifier.

(a) *Identification.* A respiratory gas humidifier is is a device used to add moisture to, and sometimes warm, the breathing gases to be administered to the patient. Cascade, gas, heated, and prefilled humidifiers are included in this generic type of device.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33424 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1747]

Medical Devices; Classification of Humidifiers for Home Use

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying humidifiers from home use into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of humidifiers for home use.

1. Identification: A humidifier for home use is a device used to add water vapor to inspired gases for respiratory therapy. The vapor produced by the device pervades the area surrounding the patient and is inspired during normal respiration.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that humidifiers for home use be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the device can be adequately cleaned and disinfected to prevent contamination of the room air with microorganisms and particulate matter. The temperature of the water reservoir must be controlled to minimize

growth of microorganisms, and to assure appropriate heating and/or humidifying of inhaled gases to prevent patient burns or hyperthermia (elevation of body temperature). The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, humidifiers. The Panel noted the development of standards by the Air Conditioning and Refrigeration Institute.

5. Risks to health: (a) Infection, allergic reaction, irritation: Inadequate cleaning, disinfection and/or temperature control in the humidifier may allow the growth of microorganisms and result in infections, allergic reactions, or irritation of the patient's airway. (b) Burns, hyperthermia: If the inhaled gases are too hot, the patient may be burned or may develop hyperthermia (elevation of body temperature).

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that humidifiers for home use be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5460, to read as follows:

§ 868.5460 Humidifier for home use.

(a) *Identification.* A humidifier for home use is a device used to add water vapor to inspired gases for respiratory therapy. The vapor produced by the device pervades the area surrounding the patient and is inspired during normal respiration.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33425 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1748]

Medical Devices; Classification of Hyperbaric Chambers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hyperbaric chambers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James. R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hyperbaric chambers:

1. Identification: A hyperbaric chamber is a device that can be pressurized to greater than atmospheric pressure. It is used to increase the environmental oxygen pressure to promote the movement of oxygen from the environment to the patient's tissue. This classification does not include those chambers used solely for topical application.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hyperbaric chambers be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure adequate strength of the chamber to prevent sudden decompression or explosion, to assure that the materials used will eliminate the possibility of fire, to assure that there are safety features to prevent overpressurization and prolonged exposure to pressure, and to assure that gases in the chamber do not become contaminated, causing infection. The Anesthesiology Device Classification Panel considered the Committee Report of the Undersea Medical Society on "Hyperbaric Oxygen Therapy" (Ref. 1) in evaluating the uses of hyperbaric chambers. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panels believe that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on a presentation at the August 17, 1977 Panel meeting by Drs. Shilling and Kindwall of the Undersea Medical Society, Inc., and a committee report by Dr. Kindwall (Ref. 1). The Panel also cited an existing standard: American

National Standards Institute/National Fire Protection Association 56D–1976, Hyperbaric Facilities (Ref. 2).

5. Risks to health: (a) Oxygen toxicity: Overpressurization or prolonged exposure may result in excessive tissue oxygen concentrations. (b) Cavitation of blood: Sudden decompression of the chamber may result in blood cavitation (bubble formation in the blood) in the patient. (c) Mechanical trauma: Fire or explosion of the chamber due to poor materials or design may cause burns to the patient. (d) Infection, irritation: If the chamber gas is contaminated, the patient may contract an infection.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the hyperbaric chambers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Kindwall, E. P., "Hyperbaric Oxygen Therapy," Committee Report, Undersea Medical Society, UMS Report Number 5–23–77.

2. American National Standards Institute/National Fire Protection Association, Hyperbaric Facilities, 56D, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 710(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5470, to read as follows:

§ 868.5470 Hyperbaric chamber.

(a) *Identification.* A hyperbaric chamber is a device that can be pressurized to greater than atmospheric pressure. It is used to increase the environmental oxygen pressure to promote the movement of oxygen from the environment to the patient's tissue. This classification does not include those chambers used solely for topical application.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33426 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1749]

Medical Devices; Classification of Hyperthermia Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hyperthermia devices into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hyperthermia devices:

1. Identification: A hyperthermia device is a soft, liquid-filled blanket and a heat exchanger used to warm all or part of the body.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the hyperthermia devices be classified into class II (performance standards) because the Panel believes that the temperature of the device must be controlled to avoid excessive heating of the patient. The Panel believes that the device should be constructed so that only the temperature probe intended for use with the device can be attached and that others will not fit. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, hyperthermia devices.

5. Risks to health: Excessive hyperthermia: Temperature control failure or the use of an improper temperature probe may cause excessive heating of the patient, resulting in burns, tissue damage, ventricular fibrillation (rapid, repetitive excitation of heart muscle without a coordinated contraction of the ventricle), or blood coagulation defects.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hyperthermia devices be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health

presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5480, to read as follows:

§ 868.5480 Hyperthermia device.

(a) *Identification.* A hyperthermia device is a soft, liquid-filled blanket and a heat exchanger used to warm all or part of the body.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33427 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1750]

Medical Devices; Classification of Hypothermia Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hypothermia devices into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hypothermia devices:

1. Identification: A hypothermia device is a liquid-filled blanket and heat exchanger used to cool all or part of the body.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hypothermia devices be classified into class II (performance standards) because the temperature of the device must be controlled to avoid excessive cooling of the patient. The Panel believes that the device should be constructed so that only the temperature probe intended for use with this device can be attached, and that others will not fit. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, hypothermia devices.

5. Risks to health: Excessive hypothermia: Temperature control failure or the use of an improper temperature probe may cause excessive cooling of the patient, resulting in tissue damage, ventricular fibrillation (rapid, repetitive excitation of heart muscle without a coordinated contraction of the ventricle), or blood coagulation defects.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hypothermia devices be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believe that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5490, to read as follows:

§ 868.5490 Hypothermia device.

(a) *Identification.* A hypothermia device is a liquid-filled blanket and heat exchanger used to cool all or part of the body.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33428 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N-1751]

Medical Devices; Classification of Automatic Catheter Flushing Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automatic catheter flushing devices into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of automatic catheter flushing devices:

1. Identification: An automatic catheter flushing device is used to pump fluid into an intravascular catheter to prevent clot formation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that automatic catheter flushing devices be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the valve mechanism adequately prevents improper infusion rates. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members; personal knowledge of, and clinical experience with, automatic catheter flushing devices.

5. Risks to health: (a) Clot formation: If the valve mechanism fails, reducing the flow rate, clots may form in the catheter and prevent infusion. (b) Overinfusion: Failure of the valve mechanism may cause an excessive flush rate, resulting in overinfusion and fluid overload to the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that automatic catheter flushing devices be classified into class II (performance standards). The agency believes that a performence standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5520, to read as follows:

§ 868.5520 Automatic catheter flushing device.

(a) *Identification.* An automatic catheter flushing device is used to pump fluid into an intravascular catheter to prevent clot formation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33429 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1752]

Medical Devices, Classification of Flexible Laryngoscopes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying flexible laryngoscopes into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Durg Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the

development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of flexible laryngoscopes:

1. Identification: A flexible laryngoscope is a fiberoptic device used to examine and visualize a patient's upper airway and to facilitate the placement of a tracheal tube.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that flexible laryngoscopes be classified into class II (performance standards) because the Panel believes the design of, and the materials used in, the device must be controlled to assure both that the patient's airway is not injured from sharp edges on the device and that the device can be adequately sterilized to prevent infection. The electrical design of the device also must be controlled to assure that the patient does not receive an electrical shock. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Trauma: Sharp edges on the device may cause trauma to the patient's airway. (b) Electrical shock: Improper electrical design may result in electrical shock of the patient. (c) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that flexible laryngoscopes be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5530, to read as follows:

§ 868.5530 Flexible laryngoscope.

(a) *Identification.* A flexible laryngoscope is a fiberoptic device used to examine and visualize a patient's upper airway and to facilitate placement of a tracheal tube.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33430 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1753]

Medical Devices; Classification of Rigid Laryngoscopes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rigid laryngoscopes into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rigid laryngoscopes:

1. Identification: A rigid laryngoscope is a device used to examine and visualize a patient's upper airway and to facilitate placement of a tracheal tube.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that rigid laryngoscopes be classified into Class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that no trauma occurs to the patient's airway from sharp edges, that the device can be adequately sterilized to prevent infection, and that the device's light source is reliable to prevent failure during emergency procedures. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel notes the development of a standard for laryngoscopy by the International Standards Organization Technical Committee 121.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, rigid laryngoscopes, which have been widely used for many years.

5. Risks to health: (a) Trauma: Sharp edges on the device may injure the patient's airway.

(b) Failure of light source: Sudden failure of the light source during placement of the tracheal tube may be hazardous to the patient because of increased difficulty in proper placement of the tracheal tube. (c) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rigid laryngoscopes be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5540, to read as follows:

§ 868.5540 Rigid laryngoscope.

(a) *Identification.* A rigid laryngoscope is a device used to examine and visualize a patient's upper airway and to facilitate placement of a tracheal tube.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33431 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1754]

Medical Devices; Classification of Anesthetic Gas Masks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthetic gas masks into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthetic gas masks:

1. Identification: An anesthetic gas mask is a device, usually made of conductive rubber, that is positioned over a patient's nose or mouth to direct anesthetic gases to the upper airway.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that anesthetic gas masks be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to assure that gas delivery to the patient is adequate and that the mask is of a proper size and shape. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, these devices and the widespread use of these devices over the past 25 years.

5. Risks to health: (a) Failure to deliver gas: Disconnection of the mask from the breathing tube may result in failure of gas delivery to the patient. (b) Inadequate delivery: Gas leakage from the mask may lead to a decrease in the volume of gas delivered to the patient. (c) Rebreathing of exhaled gases: Excessive gas volume in the device may cause the patient to rebreathe previously exhaled gas. (d) Eye injury: An improperly fitting mask may cause eye injury.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the anesthetic gas mask be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is significant experience with the device and because the risks to health associated with the device can be controlled by standardization and by following good manufacturing practices. The agency believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs

proposes to amend Part 868 in Subpart F by adding new § 868.5550, to read as follows:

§ 868.5550 Anesthetic gas mask.

(a) *Identification.* An anesthetic gas mask is a device, usually made of conductive rubber, that is positioned over a patient's nose or mouth to direct anesthetic gases to the upper airway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associated Commissioner for Regulatory Affairs.

[FR Doc. 79–33432 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1755]

Medical Devices; Classification of Gas Mask Head Straps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas mask head straps into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II (performance standards). After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of gas mask head straps:

1. Identification: A gas mask head strap is a device used to hold an anesthesia gas mask in position on a patient's face.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the gas mask head straps be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that when the device is used in an explosive atmosphere, an explosion does not occur from static electricity due to the use of non-conductive materials. The Panel also believes that a standard is necessary to prevent nerve damage which might be caused by excessive strap pressure, and to prevent dermatitis which might be caused by material that is not biocompatible or sterile. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel noted that standards are being developed by committees of the Association of Operating Room Nurses and the National Fire Protection Association.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. There has been widespread use of gas mask head straps for many years.

5. Risks to health: (a) Explosion: Static electricity from the use of nonconductive materials may cause an explosion if the device is used in an explosive environment. (b) Nerve damage: Excessive strap pressure may cause nerve damage if the strap is used for a long period of time. (c) Dermatitis: Adverse skin reaction may occur if the strap material is not biocompatible or sterile.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that gas mask head straps be classified into class I (general controls) with no exemptions. Because users are familiar with these simple devices and have used them successfully for many years without significant problems, the agency believes that a performance standard is unnecessary. The agency believes that general controls, including appropriate labeling regarding the conductivity or nonconductivity of the device and warnings against use of the nonconductive device in the presence of flammable anesthetic agents, are sufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5560, to read as follows:

§ 868.5560 Gas mask head strap.

(a) *Identification.* A gas mask head strap is a device used to hold an anesthesia gas mask in position on a patient's face.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA 305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33433 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1756]

Medical Devices; Classification of Nonrebreathing Masks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonrebreathing masks into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonrebreathing masks:

1. Identification: A nonrebreathing mask is a device fitting over the face that is used to supplement a patient's inspired oxygen. It uses one-way valves to prevent the patient from rebreathing exhaled gases.

2. Recommended classification Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the nonrebreathing masks be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to assure that the one-way valves operate properly and that the correct gas concentration is delivered to the patient. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that permarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, nonrebreathing masks. The Panel also cited the evaluation of disposable oxygen masks by the Emergency Care Research Institute (Ref. 1).

5. Risks to health: (a) Asphyxia: If the one-way valves do not operate properly, the patient could be asphyxiated due to lack of oxygen. (b) Hypoxia: If the mask fits the patient poorly, leakage could result, and dilution of the supplemental oxygen concentration may lead to patient hypoxia (insufficient oxygen).

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonrebreathing masks be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard for this device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Disposable Oxygen Masks," *Health Devices*, 6(7): 157-171, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5570, to read as follows:

§ 868.5570 Nonrebreathing mask.

(a) *Identification.* A nonrebreathing mask is a device fitting over the face that is used to supplement inspired oxygen. It utilizes one-way valves to prevent the patient from rebreathing previously exhaled gases.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33434 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1757]

Medical Devices; Classification of Oxygen Masks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oxygen masks into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the General Hospital Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These

actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the General Hospital Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of oxygen masks:

1. Identification: An oxygen mask is a device placed over the patient's nose and mouth to administer oxygen.

2. Recommended classification: The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that this device be classified into class I (general controls). The Panels recommend that there be no exemptions for this device.

3. Summary of reasons for recommendation: The Panels recommend that oxygen masks be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panels do not believe that this device requires performance standards to control the identified risks to health.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risks to health: (a) Delivery of inappropriate oxygen concentration: Excessive flow resistance may result in the delivery of an inappropriate oxygen concentration to the patient. (b) Eye injury: If the device is not of an appropriate size or shape to fit the patient, the patient's eye may be injured. The General Hospitl and Personal Use Device Classification Panel identified the following risks to health: (c) Infection: If the device is not sterile, infection may result. (d) Inadequate oxygen delivery: If the mask leaks excessively due to a poor fit, the appropriate amount of oxygen may not be delivered to the patient.

Proposed Classification

FDA agrees with the Panels' recommendation and is proposing that oxygen masks be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and drugs proposes to amend Part 868 in Supbart F by adding new § 868.5580, to read as follows:

§ 8698.5580 Oxygen mask.

(a) *Identification.* An oxygen mask is a device placed over the patient's nose and mouth to administer oxygen.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33435 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1758]

Medical Devices; Classification of Scavenging Masks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying scavenging masks into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of scavenging masks:

1. Identification: A scavenging mask is a device positioned over a patient's nose to deliver anesthetic or analgesic gases to the upper airway and to remove excess and exhaled gas. It is usually used during dentistry.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that scavenging masks be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure adequate connector fittings, which prevent leakage of gas or accidental disconnection. In addition, the Panel believes that the size and shape of the mask must be controlled to

prevent leakage of gas from the area between the face and rim of the mask and to prevent eye injury. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, scavenging masks and related devices. These devices have been widely used for many years.

5. Risks to health: (a) Failure to deliver gas: Improper connector fittings may result in partial or complete disconnection of the gas line from the mask. (b) Decrease in volume delivered: Improper connector fittings or improper fit of the mask to the face may result in leakage of gas from these areas and delivery of insufficient gas to the patient. (c) Rebreathing: Excessive volume in the mask may result in rebreathing of exhaled gases. (d) Eye injury: Improper fit of the mask to the face may result in eye injury.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that scavenging masks be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5590, to read as follows:

§ 868.5590 Scavenging mask.

(a) *Identification.* A scavenging mask is a device positioned over a patient's nose to deliver anesthetic or analgesic gases to the upper airway and to remove excess and exhaled gas. It is usually used during dentistry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33436 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1759]

Medical Devices; Classification of Venturi Masks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying venturi masks into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that the device by classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken unde rthe Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of venturi masks:

1. Identification: A venturi mask is a device containing an air-mixing mechanism used to dilute 100 percent oxygen to a predetermined concentration before delivery to a patient.

2. Recommended classification: The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that this device be classified into class II (performance standards). Both Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that the venturi mask be classified into class II (performance standards) because the Panels believe that the design of, and the materials used in, the device should be controlled to assure that the patient suffers no skin irritation from the the mask and that the mask delivers the prescribed oxygen concentration to the patient. The Panels believe that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panels believe that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the Panel members' personal knowledge of, and clinical experience with, this device, as well as its widespread use and acceptance. The Anesthesiology Device Classification Panel noted that the use of venturi masks is mentioned in all standard textbooks on respiratory therapy.

5. Risks to health: The Anesthesiology Device Classification Panel and the General Hospital and Personal Use

Device Classification Panel identified the following risks to health: (a) Inappropriate oxygen delivery: If the mask becomes disconnected from the oxygen source or if the mixing orifice is not properly constructed, the amount of breathing gas delivered to the patient may be reduced. (b) Inappropriate oxygen concentration: If the air entrainment (mixing) mechanism does not function properly, the specified oxygen concentration may be in error, causing the patient to receive too little or too much oxygen. The General Hospital and Personal Use Device Classification Panel identified the following additional risk to health: (c) Adverse tissue reaction: If the mask material is incompatible with human tissue, the patient may have an adverse skin reaction.

Proposed Classification

FDA agrees with the recommendations of both Panels and is proposing that venturi masks be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard for this device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5600, to read as follows:

§ 868.5600 Venturi mask.

(a) *Identification.* A venturi mask is a device containing an air-mixing mechanism used to dilute 100 percent oxygen to a predetermined concentration before delivery to a patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33437 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1760]

Medical Devices; Classification of Membrane Lungs for Long-Term Pulmonary Support

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying membrane lungs (for long-term pulmonary support) into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacture of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of membrane lungs for long-term pulmonary support:

1. Identification: A membrane lung is a device used to provide extracorporeal blood oxygenation for longer than 24 hours.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that membrane lung be classified into class III (premarket approval) because the Panel believes that insufficient information exists to determine the adequacy of general controls, or to establish standards, to provide reasonable assurance of the safety and effectiveness of this device, which is both life-sustaining and life-supporting.

Therefore, the device should be subject to premarket approval to assure that manufacturers satisfactorily demonstrate the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on a presentation (May 20, 1976) by Dr. Theodor Kolobow, Chief of Cardiopulmonary Assist Devices, National Heart and Lung Institute, National Institutes of Health, Bethesda, Maryland. Dr. Kolobow discussed the need for long-term pulmonary support for critically ill patients and the advantages of extracorporeal membrane oxygenation in reducing blood trauma. However, Dr. Kolobow noted that extracorporeal membrane oxgenation is a new technique and must be used under well-controlled conditions by physicians skilled and knowledgeable in its use.

5. Risks to health: (a) Thrombocytopenia: Blood platelets important to the clotting mechanism may be trapped in the device, resulting in a tendency toward increased bleeding. (b) Hemolysis: The red blood cells may be damaged by the mechanicl features of the extracorporeal circuit, or they may be damaged if materials are used that are not biocompatible. (c) Inadequate gas exchange: If proper flow and mixing properties are not used in the extracorporeal circuit, inadequate oxygen delivery and carbon dioxide removal may result.

Proposed Classification

FDA agrees with the Panel and is proposing that membrane lungs for long-

term pulmonary support be classified into class III (premarket approval). The agency believes that insufficient information exists to determine the adequacy of general controls or to establish standards, to provide reasonable assurance of the safety and effectiveness of this life-sustaining or life-supporting device. The agency also agrees with the Panel that there are not sufficient scientific and medical data to demonstrate long-term safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5610, to read as follows:

§ 868.5610 Membrane lung for long-term pulmonary support.

(a) *Identification.* A membrane lung is a device used to provide extracorporeal blood oxygenation for longer than 24 hours.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33438 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1761]

Medical Devices; Classification of Breathing Mouthpieces

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breathing mouthpieces into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of breathing mouthpieces:

1. Identification: A breathing mouthpiece is a rigid device inserted into a patient's mouth that connects with diagnostic or therapeutic respiratory devices.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that breathing mouthpieces be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the device does not have sharp edges that may lacerate the patient's mouth and that it can be cleaned adequately. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, breathing mouthpieces.

5. Risks to health: (a) Laceration: If the device has sharp edges, it could cut the patient's mouth. (b) Infection: If the device cannot be cleaned adequately, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that breathing mouthpieces be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risk to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5620, to read as follows:

§ 868.5620 Breathing mouthpiece.

(a) *Identification.* A breathing mouthpiece is a rigid device inserted into a patient's mouth that connects with diagnostic or therapeutic respiratory devices.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33439 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

Docket No. 78N-1762

Medical Devices; Classification of Nebulizers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nebulizers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nebulizers:

1. Identification: A nebulizer is a device used to add particulate liquids via a spray to inspired gases that are directly delivered to the patient. Heated, ultrasonic, gas, venturi, and refillable nebulizers are included in this generic type of device.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that nebulizers be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that the device does not promote infection due to bacteria in the device, overhydrate or dry the patient's airway due to improper fluid output, or excessively heat the patient's airway due to lack of adequate temperature control. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The Panel also cited the standard currently being developed by the Z-79 Committee of the American National Standards Instiute concerning humidifiers and nebulizers.

5. Risks to health: (a) Overhydration: The delivery of a large amount of water to the patient may result in a water overload that could be hazardous, particularly to small infants. (b) Drying of airway: If the device does not sufficiently humidify the inspired gas mixture, the patient may breath dry gas, causing drying of the patient's airway. (c) Burns or hyperthermia (elevated body temperature): Excessive heating of the inspired gas mixture by the nebulizer may lead to burns in the upper airway, trachea, and or facial areas, or to hyperthermia. (d) Infection or allergic reaction: Bacteria and other microorganisms may multiply in the warm, moist environment of the nebulizer. Inhalation of these microorganisms by the patient may result in an infection or an allergic reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nebulizers be classified into class II (performance standards). Although the device is often used in a life support system, the agency believes that the device itself if not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard for this device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5630, to read as follows:

§ 868.5630 Nebulizer.

(a) *Identification.* A nebulizer is a device used to add particulate liquids via a spray to inspired gases that are directly delivered to the patient. Heated, ultrasonic, gas, venturi, and refillable nebulizers are included in this generic type of device.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33440 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1763]

Medical Devices; Classification of Medicinal Nonventilatory Nebulizers (Atomizers)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying medicinal nonventilatory

nebulizers (atomizers) into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulations based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of medicinal nonventilatory nebulizers (atomizers):

1. Identification: A medicinal nonventilatory nebulizer (atomizer) is a device used to deliver liquid medication to a patient in aerosol form.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that medicinal nonventilatory nebulizers (atomizers) be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards to control the identified risks to health. The Panel believes that the device should be exempt from the good manufacturing practice regulation because any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Aspiration of components: If the device is poorly designed or assembled, the patient may aspirate pieces of the device.

Proposed classification

FDA agrees with the Panel recommendation and is proposing that medicinal nonventilatory nebulizers (atomizers) be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of medicinal nonventilatory nebulizers (atomizers) be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of medicinal nonventilatory nebulizers (atomizers) having defects that could harm users.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5640, to read as follows:

§ 868.5640 Medicinal nonventilatory nebulizer (atomizer).

(a) *Identification.* A medicinal nonventilatory nebulizer (atomizer) is a device used to deliver liquid medication to a patient in aerosol form.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 33441 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1764]

Medical Devices; Classification of Esophageal Obturators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying esophageal obturators into class II (performance standards). FDA is also publishing the recommendation of the Anestheosiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectivness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTRACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following

recommendation regarding the classification of esophageal obturators:

1. Identification: An esophageal obutator is a device inserted through the patient's mouth to facilitate ventilation of the patient during emergency resuscitation by occluding (blocking) the esophagus, thereby permitting positive pressure ventilation through the trachea. The device consists of a closed-end semirigid esophagael tube that is attached to a face mask.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that esophageal obturators be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to prevent the occurrence of esophageal or gastric trauma by assuring that the device is of the proper size and shape, and has no sharp edges.

The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The Panel noted that esophageal obturators are widly used in emergency medical care. The use of esophageal obturators is well accepted by the medical community, with instructional programs and literature available through the American Red Cross, the American Heart Association, and the American Medical Association.

5. Risks to health: Esophageal or gastric rutpure: If the device is not of the proper size, shape, and length, insertion into the patient could cause gastric or esophageal rupture.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that esophageal obturators be classified into class II (performance standards). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(A))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5650, to read as follows:

§ 868.5650 Esophageal obturator.

(a) *Identification.* An esophageal obturator is a device inserted through the patient's mouth to facilitate ventilation of the patient during emergency resuscitation by occluding (blocking) the esophagus, thereby permitting positive pressure ventiliation through the trachea. The device consists of a closed-end semirigid esophageal tube that is attached to a face mask.

(b) *Classification.* Class II (performance standard).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in rackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33442 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1765]

Medical Devices; Classification of Portable Liquid Oxygen Units

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying portable liquid oxygen units into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of portable liquid oxygen units:

1. Identification: A portable liquid oxygen unit is a portable, thermally insulated container of liquid oxygen that is used for supplementation of a patient's inspired oxygen. It is sometimes accompanied by tubing and an oxygen mask.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that portable liquid oxygen units be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to assure that the device reliably delivers oxygen to the patient and that is does not present a hazard of fire or explosion. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and

effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on its widespread use during the past 25 years.

5. Risks to health: (a) Burns: The use of oxygen in high concentration presents a fire hazard, with the accompanying possibility of burns. (b) Inappropriate oxygen delivery: If the oxygen is not delivered reliably, the patient may receive a breathing mixture with too low or too high an oxygen concentration.

Proposed Classification

FDA agrees with the Panel and is proposing that the portable liquid oxygen units be classified into class II (performance standards). Although this device supplies supplemental oxygen that may, in an emergency, be life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard for this device. The agency also believes that general controls are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5655, to read as follows:

§ 868.5655 Portable liquid oxygen unit.

(a) *Identification.* A portable liquid oxygen unit is a portable, thermally insulated container of liquid oxygen that is used for supplementation of a patient's inspired oxygen. It is sometimes accompanied by tubing and an oxygen mask.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associated Commissioner for Regulatory Affairs.

[FR Doc. 79-33443 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No.] 78N-1766

Medical Devices; Classification of Electric-Powered Percussors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electric-powered percussors into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of electric-powered percussors:

1. Identification: An electric-powered percussor is a device used to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that electric-powered percussors be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that the percussion stroke is not of such great force and/or length that it could break the ribs of the patient, and to assure that users of the device cannot pinch their fingers between the percussion ball and the body of the device. The electrical design must be controlled to assure that the patient or operator does not receive an electrical shock due to excessive leakage current. The Panel believes that general controls will not provide sufficient controls over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device, and on its widespread use.

5. Risks to health: (a) Broken ribs: Excessive force and/or length of the percussion stroke may cause broken ribs, particularly in elderly patients. (b) Trauma: Narrow clearance between the percussion ball and the body of the device may cause injury to the users' fingers. (c) Electrical shock: If the device is not designed properly, the patient or operator may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that electric-powered percussors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient

information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5665, to read as follows:

§ 868.5665 Electric-powered percussor.

(a) *Identification.* An electric-powered percussor is a device used to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33444 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1767]

Medical Devices; Classification of Rebreathing Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rebreathing devices into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rebreathing devices:

1. Identification: A rebreathing device is a device that enables the patient to rebreathe exhaled gases. It may be used in conjunction with pulmonary function testing or for increasing minute ventilation.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that rebreathing devices be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the good manufacturing practice regulation will not improve the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rebreathing devices be classified into class I. The Agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a rebreathing device be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device who does not label or otherwise represent it as sterile be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a rebreathing device, even when it is not labeled or otherwise represented as sterile, must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a rebreathing device must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaing files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. A manufacturer of a rebreathing device that is labeled or otherwise represented as sterile is, in the manufacture of this device, subject to the GMP regulation in its entirety.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5675, to read as follows:

§ 868.5675 Rebreathing device.

(a) *Identification.* A rebreathing device is a device that enables the patient to rebreathe exhaled gases. It may be used in conjunction with pulmonary function testing or for increasing minute ventilation.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 33445 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1768]

Medical Devices; Classification of Incentive Spirometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying incentive spirometers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of incentive spirometers:

1. Identification: An incentive spirometer is a device that indicates the patient's breathing volume or flow. The device is used to provide an incentive to patients to improve their ventilation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that incentive spirometers be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the device does not have excessive flow resistance that would cause it to display inaccurate volume or flow data, that the device structure is of adequate strength to prevent inhalation of broken or whole components of the device, that the device can be cleaned and sterilized to prevent foreign body reaction and infection, and that the electrical design is adequate to assure that users do not receive an electrical shock. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, incentive spirometers.

5. Risks to health: (a) Inappropriate therapy: If the device does not measure the patient's inspired volume or flow accurately, the device may not accurately indicate lung condition, and thereby cause the administration of inappropriate therapy to the patient. (b) Infection: Inadequate cleaning and sterilization of the device may result in patient infection. (c) Electrical shock: If the device is not designed properly, the patient may receive an electrical shock. (d) Inhalation of foreign material: Breakage of internal parts, or in adequate cleaning of the device may result in the inhalation of foreign material.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the incentive spirometer be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5690, to read as follows:

§ 868.5690 Incentive spirometer.

(a) *Identification.* An Incentive spirometer is a device that indicates the patient's breathing volume or flow. The device is used to provide an incentive to patients to improve their ventilation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associated Commissioner for Regulatory Affairs.

[FR Doc. 79-33446 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1769]

Medical Devices; Classification of Oxygen Tents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oxygen tents into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of oxygen tents:

1. Identification: An oxygen tent is a non-powered device that encloses the patient's head and upper body to contain oxygen delivered to the patient.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempted from good manufacturing practice (GMP) regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that oxygen tents be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards to control the identified risks to health. The Panel believes that the oxygen tent should be exempt from the good manufacturing practice regulations because all defects of the device are readily detectable before use.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Burns, asphyxiation: Because of the presence of high concentrations of oxygen, use of flammable materials in the device creates a potentially severe fire hazard. A fire could burn or asphyxiate the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that oxygen tents be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA disagrees with the Panel's recommendation that manufacturers of oxygen tents be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of oxygen tents having defects that could harm users.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5700, to read as follows:

§ 868.5700 Oxygen tent.

(a) *Identification.* An oxygen tent is a non-powered device that encloses the patient's head and upper body to contain oxygen delivered to the patient.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA 305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33447 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1770]

Medical Devices; Classification of Electrically-Powered Oxygen Tents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electrically-powered oxygen tents into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-

65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and the General Hospital and Personal Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of electrically-powered oxygen tents:

1. Identification: An electrically-powered oxygen tent is a device that encloses the patient's head and, via an electrically powered unit, administers inspiratory oxygen and provides control of the temperature and humidity. This generic type of device also includes the pediatric aerosol tent.

2. Recommended classification: Both the Anesthesiology Device Classification Panel and General Hospital and Personal Use Device Classification Panel recommended that the electrically-powered oxygen tent be classified into class II (performance standards). The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a low priority. The General Hospital Personal Use Device Classification Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: Both Panels recommend that electrically-powered oxygen tents be classified into class II (performance standards) because the Panels believe that the design of, and the materials used in, the device must be controlled to assure that the temperature and humidity are regulated, that the device has an alarm to warn of a drop in temperature which could cause hypothermia of the patient, and that electrical leakage current is minimized to prevent electrical shock and reduce the fire hazard. The Panels believe that general controls will not provide sufficient control over these characteristics. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the Panel members' personal knowledge of, and clinical experience with, electrically-powered oxygen tents. The device has been in widespread use for many years, and its fundamental principles and applications are well-accepted.

5. The Anesthesiology Device Classification Panel identified the following risks to health: (a) Burns and related injuries: Because of the presence of a high concentration of oxygen, use of flammable materials and electrical power in the device creates a potentially severe fire hazard. A design weakness or an operational malfunction could result in an explosion or fire, causing burns. (b) Electrical shock: If the device is not designed properly, the patient may receive an electrical shock. (c) Hypothermia: An inadequate temperature control or temperature alarm may result in hypothermia of the patient.

The General Hospital Personal Use Device Classification Panel identified the following risks to health: (a) Inadequate ventilation: Insufficient oxygen flow rate may result in inadequate ventilation and hypoxia. (b) Inadequate humidification: Insufficient humidification may result in drying of the patient's airway. (c) Hypothermia, hyperthermia: Failure of the temperature controls could result in hypothermia or hyperthermia.

Proposed classification

FDA agrees with the recommendation of the Anesthesiology Device Classification Panel and the General Hospital Personal Use Device Classification Panel and is proposing that the electrically-powered oxygen tent be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1050, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5710, to read as follows:

§ 868.5710 Electrically-powered oxygen tent.

(a) *Identification.* A electrically-powered oxygen tent is a device that encloses the patient's head and, via an electrically powered unit, administers inspiratory oxygen and provides control of the temperature and humidity. This generic type device also includes the pediatric aerosol tent.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33446 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1771]

Medical Devices; Classification of Bronchial Tubes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying bronchial tubes into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective

30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of bronchial tubes:

1. Identification: A bronchial tube is a device used to differentially intubate a bronchus (one of the two main branches of the trachea leading directly to the lung) in order to isolate a portion of the lung distal to the tube.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that bronchial tubes be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device should be controlled to assure that the device permits proper ventilation of the patient, does not cause trauma to the patient's airway, does not promote infection, and is compatible with human lung tissue. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, and its widespread use for the past 25 years.

5. Risks to health: (a) Failure to ventilate: If the bronchial tube becomes kinked, or if the cuff that isolates the portion of the lung fails, or if the bronchial tube is not of the appropriate configuration for use in a particular portion of the lung, the patient may not receive an adequate volume of breathing gas. (b) Infection: If the device is not sterile, infection may result. (c) Tissue reaction: If the bronchial tube is composed of a material that is incompatible with lung tissue, it may cause an allergic reaction. (d) Trauma: If the device is too rigid, it may cause trauma upon insertion.

Proposed Classification

FDA agrees with the Panel and is proposing that bronchial tubes be classified into class II (performance standards). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5720, to read as follows:

§ 868.5720 Bronchial tube.

(a) *Identification.* A bronchial tube is a device used to differentially intubate a bronchus (one of the two main branches of the trachea leading directly to the lung) in order to isolate a portion of lung distal to the tube.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33449 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1772]

Medical Devices; Classification of Tracheal Tubes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tracheal tubes into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tracheal tubes:

1. Identification: A tracheal tube is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that tracheal tubes be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device should be controlled to assure that the patient can be ventilated using the device, that the device is not easily occluded (blocked) by kinking or cuff problems, and that the material used in the device does not cause an allergic reaction or infection. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The device has been in widespread use during the past 25 years. The Panel also cited the development of standards for tracheal tubes by a committee of the American National Standards Institute.

5. Risks to health: (a) Failure to ventilate: Blockage of the tube due to kinking, rupture or herniation of the cuff, or improper shape may prevent ventilation of the patient. (b) Infection: If the device is not sterile, infection may result. (c) Tissue reaction: If the materials used in the device are not biocompatible, they may cause tissue reactions. (d) Trauma: If the device materials are not flexible, the patient's airway may be injured during intubation.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that tracheal tubes be classified into class II (performance standards). Although the device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5730, to read as follows:

868.5730 Tracheal tube.

(a) *Identification.* A tracheal tube is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33450 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1773]

Medical Devices; Classification of Tracheal/Bronchial Differential Ventilation Tubes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tracheal/bronchial differential ventilation tubes into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of tracheal/bronchial differential ventilation tubes:

1. Identification: An tracheal/bronchial differential ventilation tube is a device used to isolate the left or right lung for anesthesia and pulmonary function testing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that tracheal/bronchial differential ventilation tube be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the ventilation of the patient is not impaired by kinking of the tube, failure of the isolation cuff to completely seal the airway, or inappropriate shape; that the device does not injure the patient's airway because it is too rigid; and that the device is made of bio-compatible materials which cannot cause adverse tissue reaction. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of its safety and effectiveness because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' personal knowledge of, and clinical experience with, tracheal/bronchial differential ventilation tubes. The Panel noted that the standards for tracheal tubes and cuffs and tracheal tube connectors and adaptors developed by the American National Standards Institute would in large part be applicable to tracheal/bronchial differential ventilation tubes.

5. Risks to health: (a) Failure to ventilate: If the bronchial tube becomes kinked, or if the cuff that isolates the portion of the lung fails, or if the bronchial tube is not of the appropriate configuration for use in a particular portion of the lung, the patient may not receive an adequate volume of breathing gas. (b) Infection: If the device is not sterile, infection may result. (c) Tissue reaction: If the bronchial tube is composed of a material that is incompatible with lung tissue, an allergic tissue reaction may occur. (d) Trauma: If the bronchial tube is too rigid, it may damage the patient's airway during insertion.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that tracheal/bronchial differential ventilation tubes be classified into class II (performance standards). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5740, to read as follows:

§ 868.5740 Tracheal/bronchial differential ventilation tube.

(a) *Identification.* An tracheal/bronchial differential ventilation tube is a device used to isolate the left or the right lung for anesthesia and pulmonary function testing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33451 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1774]

Medical Devices; Classification of Inflatable Tracheal Tube Cuffs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying inflatable tracheal tube cuffs into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of inflatable tracheal tube cuffs:

1. Identification: An inflatable tracheal tube cuff is a device used to provide an airtight seal between the tracheal tube and the patient's trachea.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that inflatable tracheal tube cuffs be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the cuff is permanently fixed to the tracheal tube to prevent it from falling off and obstructing the patient's airway, that the cuff is properly inflated for adequate ventilation and protection of the patient's upper airway, that the device is of the proper size and shape to prevent injury to the patient's laryngeal and tracheal walls, and that the device is biocompatible to prevent allergic tissue reaction. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, inflatable tracheal tube cuffs. Tracheal tubes have been widely used for the past 100 years. The Panel also noted the publication of a standard for tracheal tubes and cuffs by the American National Standards Institute Z–79 Committee (Ref. 1).

5. Risks to health: (a) Airway obstruction: If the cuff comes off the tracheal tube, it may become lodged in the airway and obstruct airflow. (b) Inadequate ventilation: If the cuff fails to inflate, the patient will not receive adequate ventilation through the tracheal tube, and the upper airway will not be adequately protected. (C) Tissue reaction: If the cuff is composed of a material that is not compatible with the tissues of the trachea, an allergic tissue

reaction may occur. (d) Trauma: If the cuff is not of the proper size, shape, or length, the laryngeal and/or tracheal walls may be damaged.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the inflatable tracheal tube cuff be classified into class II (performance standards). Although the device is life supporting, the agency believes that class III premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. American National Standards Institute, "Tracheal Tubes and Cuffs," Z-79.1, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(A))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5750, to read as follows:

§ 868.5750 Inflatable tracheal tube cuff.

(a) *Identification.* An inflatable tracheal tube cuff is a device used to provide an airtight seal between the tacheal tube and the patient's trachea.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33452 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1775]

Medical Devices; Classification of Cuff Spreaders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cuff spreaders into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of cuff spreaders:

1. Identification: A cuff spreader is a device used to install tracheal tube cuffs on tracheal and tracheotomy tubes.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempted from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that cuff spreaders be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The physician can easily determine whether the device is safe and effective by examining it.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cuff spreaders be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a cuff spreader be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device who does not label or otherwise represent it as sterile be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a cuff spreader, even when it is not labeled or otherwise represented as sterile, must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a cuff spreader must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine

whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. A manufacturer of a cuff spreader that is labeled or otherwise represented as sterile is, in the manufacture of this device, subject to the GMP regulation in its entirety.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5760, to read as follows:

§ 868.5760 Cuff spreader.

(a) *Identification.* A cuff spreader is a device used to install tracheal tube cuffs on tracheal and tracheotomy tubes.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33453 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1776]

Medical Devices; Classification of Tracheal Tube Fixation Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tracheal tube fixation devices into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tracheal tube fixation devices:

1. Identification: A tracheal tube fixation device is a device used to hold a tracheal tube in place, usually by means of straps or pinch rings.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that tracheal tube fixation devices be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the patient is properly ventilated, the device does not cause tissue damage upon insertion, and the device is composed of biocompatible materials. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device, and its widespread use and acceptance in the medical community.

5. Risks to health: (a) Inadequate ventilation: If the device fails to hold the tracheal tube in place, the patient may be inadequately ventilated. (b) Tissue raction: If the tracheal tube holder is composed of a material that is not compatible with body tissues, an allergic tissue reaction may occur. (c) Trauma: If the fixation device is too rough or abrasive, it may cause trauma to the patient upon insertion.

Proposed Classification

FDA agrees with the Panel and is proposing that the tracheal tube fixation devices be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5770, to read as follows:

§ 868.5770 Tracheal tube fixation devices.

(a) *Identification.* A tracheal tube fixation device is a device used to hold a tracheal tube in place, usually by means of straps or pinch rings.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may

submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33454 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1777]

Medical Devices; Classification of Tube Introduction Forceps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tube introduction forceps into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become 78-1377 effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8747 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tube introduction forceps:

1. Identification: A tube introduction forcep (e.g., Magill forceps) is a right-angled device used to grasp a tracheal tube and place it in the patient's trachea

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that tube introduction forceps be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the tracheal tube is not damaged or the patient's airway injured from sharp edges on the device. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, tube introduction forceps. This device has been widely used for many years.

5. Risks to health: Trauma: Sharp edges on the device may cause trauma to the patient's airway or the tracheal tube.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that tube introduction forceps be classfied into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5780, to read as follows:

§ 868.5780 Tube introduction forceps.

(a) *Identification.* A tube introduction forcep (e.g., Magill forceps) is a right-angled device used to grasp a tracheal tube and place it in the patient's trachea.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m. Monday through Friday.

Dated: October 9, 1979

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33455 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1778]

Medical Devices; Classification of Tracheal Tube Stylets

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tracheal tube stylets into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tracheal tube stylets:

1. Identification: A tracheal tube stylet is a device used to make a flexible tracheal tube rigid in order to facilitate intubation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that tracheal tube stylets be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the patient's airway is not injured due to improper tip shape or length of the device, and to assure that the device can be sterilized to prevent infection. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, tracheal tube stylets.

5. Risks to health: (a) Trauma: Improper tip shape or length may injure the patient's airway. (b) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the tracheal tube stylets be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are sufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5790, to read as follows:

§ 868.5790 Tracheal tube stylet.

(a) *Identification.* A tracheal tube stylet is a device used to make a flexible tracheal tube rigid in order to facilitate intubation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 33456 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1870]

Medical Devices; Classification of Airway Connectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying airway connectors into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administation, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of airway connectors:

1. Identification: An airway connector is a device used to connect a breathing gas source to a tracheal tube, tracheotomy tube, or mask.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that airway connectors be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that leakage, disconnection, or obstruction of the connector does not occur during use. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, airway

connectors. This device is widely used and accepted. In addition, the Z–79 Committee of the American National Standards Institute has developed a standard for tracheal tube connectors and adaptors (Ref. 1).

5. Risks to health: Inadequate ventilation: Disconnection, separation, or obstruction of the connector during use may result in inadequate ventilation of the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that airway connectors be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself it not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. American National Standards Institute, Tracheal Tube Connectors and Adaptors, Z—79.2, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C 360c, 371(as))) and under authority delegated to him (21 CFR 5.12), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5810, to read as follows:

§ 868.5810 Airway connector.

(a) *Identification.* An airway connector is a device used to connect a breathing gas source to a tracheal tube, tracheotomy tube, or mask.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. to 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33457 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1781]

Medical Devices; Classification of Dental Protectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental protectors into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administation, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental protectors:

1. Identification: A dental protector is a device used to protect the patient's teeth during intubation or other manipulative procedures within the oral cavity.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that dental protectors be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that no trauma occurs to the teeth because of the improper size, shape, length, or surface qualities of the device, and that the patient does not contact an infection because of inadequate sterilization of the device. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental protectors.

5. Risks to health: (a) Trauma to teeth: Improper size, shape, length, or surface qualities of the device may result in injury to the patient's teeth. (b) Infection: Improper sterilization may result in infection.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental protectors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5820, to read as follows:

§ 868.5820 Dental protector.

(a) *Identification.* A dental protector is a device used to protect the patient's

teeth during intubation or other manipulative procedures within the oral cavity.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33458 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1782]

Medical Devices; Classification of Autotransfusion Apparatus

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying autotransfusion apparatus into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of autotransfusion apparatus:

1. Identification: An autotransfusion apparatus is a device that may consist of a roller pump, nylon mesh filter, reservior, and auxilliary filter used to collect and reinfuse a patient's blood during surgery.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class III (premarket approval) because the Panel believes that the device is life sustaining and that the hazards presented by the device cannot presently be controlled by a standard. At the Anesthesiology Device Classification Panel meeting of July 16, 1977, the Panel recommended that this device be classified into class II (performance standards) because the Panel believed that the blood pumping techniques were similar to those used with cardiovascular bypass systems. The Panel at that time believed that there was sufficient information available on cardiovascular bypass systems so that standards could be written. However, on August 9, 1978, the Panel reassessed its recommendation on the autotransfusion apparatus and recommended that it be classified into class III (premarket approval) because the hazards presented by the device, particularly air emboli, cannot at this time be controlled by a standard. Therefore, the device should be subject to premarket approval to ensure that manufacturers satisfactorily demonstrate the safety and effectiveness of this device.

4. Risks to health: (a) Emboli (vascular obstruction caused by a bit of matter foreign to the blood stream, e.g., air bubbles, blood clots, etc.): Vascular obstruction from particulate matter or air bubbles may result from inadequate blood filtration or the introduction of air into the patient's circulatory system. (b) Hemolysis: Damage to red blood cells may occur from improper materials used in the apparatus (e.g., materials not biocompatible with blood) and/or the mechanical features of the extracorporeal circuit. (c) Coagulopathy: The patient may develop a blood coagulation problem from the anticoagulant therapy possibly suggested for use with the device. (d) Infection: Infection may result from inadequate sterilization of the apparatus.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the autotransfusion apparatus be classified into class III (premarket approval). The agency believes the device presents a potential unreasonable risk of illness or injury because the hazards presented by the device, particularly air emboli, cannot be controlled by a standard. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5830, to read as follows:

§ 868.5830 Autotransfusion apparatus.

(a) *Identification.* An autotransfusion apparatus is a device that may consist of a roller pump, nylon mesh filter, reservoir, and auxilliary filter used to collect and reinfuse a patient's blood during surgery.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33459 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1783]

Medical Devices; Classification of Blood Transfusion Microfilters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood transfusion microfilters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of blood transfusion microfilters:

1. Identification: A blood transfusion microfilter is a device used to remove microaggregates (small particles) from blood or blood products during transfusion.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that blood transfusion microfilters be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the filtration surface area is adequate to prevent premature clogging and excessive flow resistance, that the effective pore size is correct to prevent passage of harmful microaggregates and pressure extrusion of trapped particles, and that the filter is compatible with blood to prevent hemolysis (destruction of red blood cells). The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted the development of a blood transfusion microfilter standard by a committee of the Association for the Advancement of Medical Instrumentation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, blood transfusion microfilters.

5. Risks to health: (a) Hemolysis: The use of materials that are not biocompatible with blood or improperly designed could cause hemolysis (destruction of red blood cells). (b) Embolic complications: Excessively large effective pore size may allow harmful microaggregates (particles) to enter the patient's vascular system and cause harmful alterations in brain and lung function. (c) Inadequate delivery: Inadequate filter surface area may cause excessive flow resistance or premature clogging of the filter that may result in inadequate blood delivery to the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that blood transfusion microfilters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5840 as follows:

§ 868.5840 Blood transfusion microfilter.

(a) *Identification.* A blood transfusion microfilter is a device used to remove microaggregates (small particles) from blood or blood products during transfusion.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33460 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1784]

Medical Devices; Classification of Pressure Tubing and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pressure tubing and accessories into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These

actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of pressure tubing and accessories:

1. Identification: Pressure tubing and accessories are flexible or rigid devices used to deliver pressurized medical gases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that pressure tubing and accessories be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to prevent leakage, occlusion, or inadvertent disconnection, causing disruption of gas flow to the patient. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necesary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device, and the widespread use of this device by medical and paramedical personnel.

5. Risks to health: Inadequate ventilation: Disconnection or occlusion of the tubing or leakage of gas from the tubing could result in inadequate ventilation of the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that pressure tubing and accessories be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5860, to read as follows:

§ 868.5860 Pressure tubing and accessories.

(a) *Identification.* Pressure tubing and accessories are flexible or rigid devices used to deliver pressurized medical gases.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33461 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N–1785]

Medical Devices; Classification of Nonrebreathing Valves

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonrebreathing valves into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nonrebreathing valves:

1. Identification: A nonrebreathing valve is a one-way valve that directs inspiratory gas flow to the patient and vents exhaled gasses into the atmosphere.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel

recommends that nonrebreathing valves be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that the device does not increase the amount of effort necessary for breathing, or prevent adequate patient ventilation. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The fundamental principles and applications of this device are well accepted and have been widely used during the past 20 years.

5. Risks to health: (a) Rebreathing of breathing gas: If the valve is improperly assembled or fails to provide for one-way gas flow, the patient may rebreathe exhaled gas. (b) Inadequate ventilation: If the valve leaks, the volume of breathing gas delivered to the patient may be decreased, leading to inadequate ventilation. (c) Increased breathing effort: If a valve presents high resistence to gas flow, the patient may be forced to use unnecessary effort to breathe. (d) Occlusion: If the valve is not assembled properly, it may become occluded (blocked), preventing the flow of gas.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonrebreathing valves be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide rasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5870, to read as follows:

§ 868.5870 Nonrebreathing valve.

(a) *Identification.* A nonrebreathing valve is a one-way valve that directs inspiratory gas flow to the patient and vents exhaled gases into the atmosphere.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33462 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1786]

Medical Devices; Classification of Anesthetic Vaporizers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthetic vaporizers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Room 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthetic vaporizers:

1. Identification: An anesthesia vaporizer is a device used to vaporize liquid anesthetic and deliver a controlled amount of the vapor to the patient.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that anesthetic vaporizers be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the patient receives the proper anesthetic dose and that the device can be cleaned and sterilized to prevent contamination. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted the development of standards for anesthesia equipment by the committees of the American National Standard Institute and the Canadian Standards Association.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. Anesthesia vaporizers have been widely used for more than 25 years.

5. Risks to health: (a) Overdose: Loose or sticking controls, overfilling of the vaporizer, foaming of the anesthetic agent, reversed flow, reversed connection, or inaccurate calibration

may cause an anesthetic overdose that could endanger the patient's life. (b) Infection: If the device is not sterile, infection may result. (c) Tissue reaction: If the device is not adequately cleaned, an allergic tissue reaction may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anesthetic vaporizers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5880, to read as follows:

§ 868.5880 Anesthetic vaporizer.

(a) *Identification.* An anesthesia vaporizer is a device used to vaporize liquid anesthetic and deliver a controlled amount of the vapor to the patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Room 4065, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33463 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N–1787]

Medical Devices; Classification of Continuous Ventilators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying continuous ventilators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulations based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of continuous ventilators:

1. Identification: A continuous ventilator (respirator) is a device used to mechanically control or assist patient breathing. The device may deliver a predetermined percentage of oxygen in the inspired gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

2. Recommended classification: The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that this device be classified into class II (performance standards). Both Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: Both the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that continuous ventilators be classified into class II (performance standards) because the Panels believe the design of the device must be controlled to assure that the appropriate breathing gas is delivered to the patient at the prescribed volume, pressure, and concentration to adequately ventilate the patient. Both Panels believe that general controls will not provide sufficient control over these characteristics. Although continuous ventilators are life supporting, both Panels believe that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the devices because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on their Panel members' personal knowledge of, and clinical experience with, these devices, which have been in use for over 30 years. In addition the Z–79 Committee of the American National Standards Institute has written a standard for breathing machines for medical use (Ref. 1).

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risks to health: (a) Inappropriate ventilation: Improper pressure adjustment may result in delivery to the patient's lungs of a reduced amount of air (hypoventilation), an increased amount of air (hyperventilation), and/or an improper mixture of breathing gas. The General Hospital and Personal Use Device Classification Panel identified the following risks to health: (b) Hypoxia or hyperoxia: The patient may receive too little or too much oxygen due to failure of the valves, meter connections, or gas concentration controls of the device. (c) Infection: If the device is not adequately cleaned or sterilized, the patient may contract an infection.

Proposed Classification

FDA agrees with the recommendation of both Panels and is proposing that

continuous ventilators be classified into class II (performance standards). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

References

1. American National Standards Institute, Breathing Machines for Medical Use, Z–79.7, 1976.

Therefore under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5895 as follows:

§ 868.5840 Continuous ventilator.

(a) *Identification.* A continuous ventilator (respirator) is a device used to mechanically control or assist patient breathing. The device may deliver a predetermined percentage of oxygen in the inspired gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33464 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1788]

Medical Devices; Classification of Noncontinuous Ventilators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying noncontinuous ventilators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulations based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of noncontinuous ventilators:

1. Identification: A noncontinuous ventilator is a device used to deliver intermittently an aerosol (suspension of liquid particles in gas) to a patient's lungs and/or to augment a patient's breathing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that noncontinuous ventilators be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that the appropriate breathing gas is delivered to the patient at the prescribed concentration, volume, and pressure. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, noncontinuous ventilators. The performance and safety of this device has been shown during 20 years of use. In addition, the Z–79 Committee of the American National Standards Institute has written a standard for breathing machines for medical use (Ref. 1).

5. Risks to health: (a) Inadequate ventilation or overdistension of lung: Uncontrolled variations in the cycling of the machine or the time allowed for inspiration or expiration may result in either the patient not receiving sufficient breathing gas or the development of excessive pressure in the lungs resulting in overdistension and rupture of lung tissue. (b) Inappropriate gas concentrations: If the air/oxygen mixing system is inaccurate, the patient may breathe a mixture too high or too low in oxygen concentration.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that noncontinuous ventilators be classified into class II. Although this device aids ventilation, it is used as adjunctive therapy and is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. American National Standards Institute, Breathing Machines for Medical Use, Z–79.7, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21

U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5905 to read as follows:

§ 868.5905 Noncontinuous ventilator.

(a) *Identification.* A noncontinuous ventilator is a device used to deliver intermittently an aerosol (suspension of liquid particles in gas) to a patient's lungs and/or to augment a patient's breathing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33465 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1789]

Medical Devices; Classification of Manual Emergency Ventilators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying manual emergency ventilators into class II (performance standards). FDA is also publishing the recommendations of both the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and the General Hospital and Personal Use Device Panel, FDA advisory committees, made the following recommendations regarding the classification of manual emergency ventilators:

1. Identification: A manual emergency ventilator is a device, usually incorporating a bag and valve, used to provide emergency respiratory support via a face mask or a tube inserted into a patient's airway.

2. Recommended classification: Both the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that manual emergency ventilators be classified into class II (performance standards). The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a high priority. The General Hospital and Personal Use Device Classification Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: Both Panels recommend that manual emergency ventilators be classified into class II (performance standards) because the Panels believe that the design of the device should be controlled to assure that the device delivers an adequate volume of air and/or oxygen to the patient. Both Panels believe that general controls will not provide sufficient control over these characteristics. Both Panels believe that although this device is life supporting, premarket approval is unnecessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: Both Panels based their recommendation on their extensive personal knowledge of, and clinical experience with, manual emergency ventilators. Manual emergency ventilators have been used extensively for more than 25 years in treating critically ill patients.

5. Risks to health: Both Panels identified the following risks to health: Inadequate ventilation: Obstruction or improper operation of the valve, leaks, misassembly of the device, poor fit of the mask over the patient's face, or an inadequate volume of air/oxygen delivered to the mask may result in the patient receiving too little breathing gas at the wrong volume and/or rate. The General Hospital Device Classification Panel identified the following additional risk to health: Infection: Inability to adequately clean and sterilize the device may result in infection.

Proposed Classification

FDA agrees with both Panel recommendations and is proposing that manual emergency ventilators be classified into class II (performance standards). The agency has reviewed both Panel recommendations and has obtained additional information concerning the use of manual emergency ventilation devices. The National Academy of Sciences—National Research Council has reviewed the field of cardiopulmonary resuscitation from the standpoint of training, principles, and practice (Ref. 1). Design criteria for cardiopulmonary resuscitation equipment have emerged from their proceedings. In May 1973, the American Heart Association and the National Academy of Sciences—National Research Council cosponsored a conference on Standards for Cardiopulmonary Resuscitation and Emergency Cardiac Care. The Council recommended certain minimum criteria for manually operated devices (Ref. 2). A performance evaluation of some commercially available manually operated resuscitators has been conducted by the Emergency Care Research Institute, and certain design criteria have been suggested (Ref. 3). Although this device is life supporting, the agency believes that Class III (premarket approval) is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "National Academy of Sciences—National Research Council: Cardiopulmonary Resuscitation Conference Proceedings," pp. 69–84, 124–132, 1976.

2. American Heart Association/National Academy of Sciences—National Research Council, "Standards for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC)," *in Journal of the American Medical Association,* 227(7), supp., 1974.

3. "Manually Operated Resuscitators," *Health Devices,* 1(1):13–17, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 869.5915, to read as follows:

§ 868.5915 Manual emergency ventilator.

(a) *Identification.* A manual emergency ventilator is a device, usually incorporating a bag and valve, used to provide emergency respiratory support via a face mask or a tube inserted into a patient's airway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulator Affairs.

[FR Doc. 79–33486 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N–1790]

Medical Devices; Classification of Powered Emergency Ventilators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered emergency ventilators into class II (performance standards). FDA is also publishing the recommendations of the Anesthesiology Device Classification Panel and the Dental Device Classification Panel that powered emergency ventilators be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the Dental Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of powered emergency ventilators:

1. Identification: A powered emergency ventilator is a demand valve or inhalator used to provide emergency respiratory support via a facemask or a tube inserted into a patient's airway.

2. Recommended classification: The Anesthesiology Device Classification Panel and the Dental Device Classification Panel recommend that this device be classified into class II (performance standards). The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a high priority. The Dental Device Classification Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: Both Panels recommend that powered emergency ventilators be classified into class II (performance standards) because the Panels believe that the design of, and the materials used, in the device must be controlled to assure that the breathing gas is delivered to the patient at the prescribed concentration, volume, pressure, and rate. The Panels believe that general controls will not provide sufficient control over these characteristics. The Panels believe that although powered emergency ventilators are life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of this device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Anesthesiology Device Classification Panel and the Dental Device Classification Panel based their recommendation on the Panel members' personal knowledge of, and clinical experience with, powered emergency ventilators. Powered emergency ventilators have been used extensively for more than 25 years in treating critically ill patients.

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risks to health: (a) Inadequate ventilation: Obstruction or failure of the valves, leaks, or missassembly of the device may result in the patient receiving too little breathing gas at the wrong volume and/or rate. (b) Pneumothorax: Overpressurization may cause overdistention of the patient's lungs (pneumothorax). (c) Collapsing of airways: The use of negative pressure in the expiratory phase may cause collapse of the patient's airways. The Dental Device Classification Panel identified the following risk to health: Failure to resuscitate: Improper design of the unit may cause it to malfunction, and this could result in failure to resuscitate the patient.

Proposed Classification

FDA agrees with the recommendation of both Panels and is proposing that

powered emergency ventilators be classified into class II (performance standards). The agency has reviewed both Panels' recommendations and has obtained additional information concerning the use of powered emergency ventilators. The National Academy of Sciences—National Research Council has reviewed the field of cardiopulmonary resuscitation from the standpoints of training, principles, and practice (Ref. 1). From the Council's proceedings emerged certain design criteria for cardiopulmonary resuscitation equipment. In May 1973, the American Heart Association and the National Academy of Sciences—National Research Council co-sponsored a Conference on Standards for Cardiopulmonary Resuscitation and Emergency Cardiac Care. The Conference recommended that pressure-cycled automatic resuscitators not be used in conjunction with external cardiac compression because compression may prematurely terminate the inflation cycle of the resuscitator, resulting in inadequate patient ventilation (Ref. 2). A performance evaluation of some commercially available oxygen-powered resuscitators has been conducted by the Emergency Care Research Institute and certain design criteria have been suggested (Ref. 3). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "National Academy of Sciences—National Research Council: Cardiopulmonary Resuscitation Conference Proceedings," pp. 69–84, 124–132, 1976.

2. American Heart Association/National Research Council, "Standards for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC)," *Journal of the American Medical Association,* 227(7), Supp., 1974.

3. "Oxygen-powered Resuscitators," *Health Devices,* 3(9):207–221, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5925 as follows:

§ 868.5925 Powered emergency ventilator.

(a) *Identification.* A powered emergency ventilator is a demand valve or inhalator used to provide emergency respiratory support via a facemask or a tube inserted into a patient's airway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33467 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1791]

Medical Devices; Classification of External Negative Pressure Ventilators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying external negative pressure ventilators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of external negative pressure ventilators:

1. Identification: An external, negative pressure ventilator (e.g., iron lung, cuirass) is a chamber that supports ventilation by using repetitive applications of external negative pressure over the diaphragm and upper trunk.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation. The Panel recommends that external negative pressure ventilators be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that there is no mechanical failure, which could cause inadequate ventilation of the patient. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, which has been in widespread use over 50 years. Use of the device is a standard therapeutic modality for polio victims and is referenced in most texts.

5. Risks to health: Inadequate ventilation: If a mechanical failure occurs, or if an adequate air seal is not maintained, the patient may receive inadequate ventilation.

Proposed Classification

FDA agrees with the Panel and is proposing that external negative pressure ventilators be classified into class II (performance standards). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5935, to read as follows:

§ 868.5935 External negative pressure ventilator.

(a) *Identification.* An external, negative pressure ventilator (e.g., iron lung, cuirass) is a chamber that supports ventilation by using repetitive applications of external negative pressure over the diaphragm and upper trunk.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk document number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33468 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N–1793]

Medical Devices, Classification of Intermittent Mandatory Ventilation Attachments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intermittent mandatory ventilation attachments into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of intermittent mandatory ventilation attachments:

1. Identification: An intermittent mandatory ventilation (IMV) attachment is a device attached to a mechanical ventilator that allows spontaneous breathing by the patient while providing mechanical ventilation at a preset rate.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that intermittent mandatory ventilation attachments be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure proper action of the valves to prevent insufficient ventilation of the patient or overdistention of the patient's lung tissues from excessive pressure. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, classification into class III (premarket approval) is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, intermittent mandatory ventilation attachments. This device is widely accepted as a primary therapeutic modality.

5. Risks to health: (a) Inadequate ventilation: Malfunction of the one-way valves or inadequate pressure generated by the device in the patient circuit may lead to inadequate ventilation of the patient. (b) Lung damage: Excessive pressure generated by the device in the patient circuit could result in overdistension of lung tissue, which may lead to lung damage.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that intermittent mandatory ventilation (IMV) attachments be classified into class II (performance standards). The agency has reviewed the Panel recommendation and has sought additional information concerning the use of intermittent mandatory ventilation attachments. The advantages and disadvantages of IMV therapy have been reviewed in the literature (Refs. 1 and 2). An IMV attachment is essentially a timer that cycles a ventilator to deliver a breath to the patient at a preset rate. As such, many IMV devices have been homemade, increasing the possibility of improper assembly. As an increasing number of manufacturers incorporate IMV circuits into their ventilators, this problem should decrease (Ref. 1). Yestingsmeier and Miller evaluated an IMV attachment not incorporated into a ventilator, for its dependability and accuracy, and

determined it to be acceptable (Ref. 3). Modifications of IMV circuits called intermittent demand ventilation (IDV) and synchronized intermittent mandatory ventilation (SIMV) have been produced. The purpose of these circuits is to associate IMV with a more normal physiology. Shapiro et al. reported favorably on IDV as a therapeutic technique (Ref. 4).

Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Kirby, R. R., D. Desautels, J. H. Modell, and R. A. Smith, "Mechanical Ventilation," *in* "Respiratory Care: A Guide to Clinical Practice," Edited by Burton, G. G., G. M. Gee, J. E. Hodgkin, and J. B. Lippincott, Philadelphia, 1977.

2. Egan, D. F., "Fundamentals of Respiratory Therapy," C. V. Mosby, St. Louis, pp. 428–432, 1977.

3. Yestingsmeier, J., and W. F. Miller, "Evaluation of IMV Controller for Accuracy, Dependability, and Adaptability," *Respiratory Care*, 21(2):145–147, 1976.

4. Shapiro, B. A., R. A. Harrison, J. R. Walton, and R. Davison, "Intermittent Demand Ventilation (IDV): A New Technique for Supporting Ventilation in Critically Ill Patients," *Respiratory Care*, 21(6):521–525, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5955, to read as follows:

§ 868.5955 Intermittent mandatory ventilation attachment.

(a) *Identification.* An intermittent mandatory ventilation (IMV) attachment is a device attached to a mechanical ventilator that allows spontaneous breathing by the patient while providing mechanical ventilation at a preset rate.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before (January 2, 1980) submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33469 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1794]

Medical Devices; Classification of Positive End Expiratory Pressure Breathing Attachments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying positive and expiratory pressure (PEEP) attachments into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of positive and expiratory pressure (PEEP) breathing attachments:

1. Identification: A positive end expiratory pressure (PEEP) breathing attachment is a device attached to a ventilator that is used to elevate pressure in a patient's lungs above atmospheric pressure at the end of exhalation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that PEEP breathing attachments be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the device does not cause excess pressure to develop in the patient's lungs, and that the device develops adequate pressure to prevent patient hypoxia (lack of oxygen). The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device. The device is currently in widespread use.

5. Risks to health: (a) Excessive pressure: If the device creates excessive pressure in the patient circuit, overdistension of the lung with barotrauma (rupture of lung tissue), pneumothorax (air in the lung cavity), and/or a reduction in cardiac output (blood flow) may result. (b) Hypoxia: Inadequate gas pressure in the patient circuit may result in patient hypoxia (lack of oxygen).

Proposed Classification

FDA agrees with the Panel and is proposing that positive and expiratory pressure (PEEP) breathing attachments

be classified into class II (performance standards). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to contrtol the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5965, to read as follows:

§ 868.5965 Positive end expiratory pressure breathing attachment.

(a) *Identification.* A positive end expiratory pressure (PEEP) breathing attachment is a device attached to a ventilator that is used to elevate pressure in a patient's lungs above atmospheric pressure at the end of exhalation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33470 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1795]

Medical Devices; Classification of Ventilator Tubing

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ventilator tubing into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ventilator tubing:

1. Identification: Ventilator tubing is a device used as a conduit for gases between the ventilator and the patient during mechanical ventilation of a patient.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ventilator tubing be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to prevent leakage through the tubing or disconnection of the tubing from other components in the breathing system. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, ventilator tubing. The Panel also cited the ongoing development of a standard for breathing tubes by the Z–79 Committee of the American National Standards Institute.

5. Risk to health: Inadequate ventilation: If the breathing tube components do not fit together properly, gas leakage or complete disconnection may occur, leading to inadequate ventilation of the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ventilator tubing be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5975 as follows:

§ 868.5975 Ventilator tubing.

(a) *Identification.* Ventilator tubing is a device used as a conduit for gases between the ventilator and the patient during mechanical ventilation of a patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between

9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33471 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1796]

Medical Devices; Classification of Tee Drains (Water Traps)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tee drains (water traps) into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tee drains (water traps):

1. Identification: A tee drain (water trap) is a device that traps and drains water that collects in ventilator tubing during respiratory therapy, thereby preventing an increase in breathing resistance.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the tee drain (water trap) be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that standard connector fittings are used to prevent gas leakage. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Inadequate ventilation: Improper size of the connector fittings or inadequate sealing of components may allow gas leakage from the device, leading to inadequate patient ventilation. (b) Inadequate drainage: Improper positioning of the water trap above the patient's airway may cause inadequate drainage of the breathing circuit.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that tee drains (water traps) be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5995, to read as follows:

§ 868.5995 Tee drain (water trap).

(a) *Identification.* A tee drain (water trap) is a device that traps and drains water that collects in ventilator tubing during respiratory therapy, thereby preventing an increase in breathing resistance.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33472 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1797]

Medical Devices; Classification of Anesthetic Cabinets, Tables, or Trays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthetic cabinets, tables, or trays into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of anesthetic cabinets, tables, or trays:

1. Identification: An anesthetic cabinet, table, or tray is a device used to store anesthetic equipment and drugs. The device is usually constructed to eliminate build-up of static electrical charges.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that anesthetic cabinets, tables, or trays be classified into class II because it believes that the designs and materials used in the devices must be controlled to assure that the devices are constructed to reduce the risk of explosion caused by the build-up of static electrical charges. The design and materials should also be controlled to assure that the devices are stable and do not cause injury by falling on patients or users. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The Panel noted that appropriate sections of the conductivity standards of the National Fire Protection Association and Underwriters Laboratories may be relevant to these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices.

5. Risks to health: (a) Burns, related injuries: If there is inadequate electrical conductivity throughout the device, burns and related injuries may occur from an explosion due to build-up of static electrical charges in the presence of flammable gases.

(b) Trauma: Poor stability may allow the device to fall on someone, causing injury.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that anesthetic cabinets, tables, or trays be classified into class I (general controls) with no exemptions. Because users are familiar with these simple devices and have used them successfully for many years without significant problems, the agency believes that a performance standard is unnecessary. The agency believes that general controls, including appropriate labeling regarding the conductivity or nonconductivity of the device and warnings against use of the nonconductive device in the presence of flammable anesthetic agents, are sufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6100, to read as follows:

§ 868.6100 Anesthetic cabinet, table, or tray.

(a) *Identification.* An anesthetic cabinet, table, or tray is a device used to store anesthetic equipment and drugs. The device is usually constructed to eliminate build-up of static electrical charges.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33473 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1798]

Medical Devices; Classification of Cardiopulmonary Emergency Carts

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary emergency carts into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Devise Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–340), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary emergency carts:

1. Identification: A cardiopulmonary emergency cart is a device used to store and transport resuscitation supplies. The device is related to the delivery of

proper emergency treatment, but it does not include any equipment used in cardiopulmonary resuscitation.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary emergency carts be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that manufacturers not be required to comply with the good manufacturing practice requirements because any defect in the device will not result in a device failure having an adverse effect on the patient.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cardiopulmonary emergency carts be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a cardiopulmonary emergency cart be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a cardiopulmonary emergency cart must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a cardiopulmonary emergency cart must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6175, to read as follows:

§ 868.6175 Cardiopulmonary emergency cart.

(a) *Identification.* A cardiopulmonary emergency cart is a device used to store and transport resuscitation supplies. The device is related to the delivery of proper emergency treatment, but it does not include any equipment used in cardiopulmonary resuscitation.

(b) *Classification.* Class I (*general controls).* The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.180, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33474 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1799]

Medical Devices; Classification of Nose Clips

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nose clips into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nose clips:

1. Identification: A nose clip is a device used to close the external nares (nostrils) during diagnostic or therapeutic procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel

recommends that nose clips be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that manufacturers not be required to comply with the good manufacturing practice requirements. The device presents no risks to health, and the integrity of the device can easily be determined by examination.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nose clips be classified into class I (general controls) because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a nose clip be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a nose clip must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a nose clip must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6225, to read as follows:

§ 868.6225 Nose clip.

(a) *Identification.* A nose clip is a device used to close the external nares (nostrils) during diagnostic or therapeutic procedures.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulator Affairs.

[FR Doc. 79–33475 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 868]

[Docket No. 78N–1800]

Medical Devices; Classification of Portable Air Compressors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying portable air compressors into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of portable air compressors:

1. Identification: A portable air compressor is a device used to provide compressed air for medical use, e.g., to drive ventilators and other respiratory equipment.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that portable air compressors be classified into class II (performance standards) because the Panel believes that the design and materials used in the device must be controlled to assure that the device reliably delivers adequate pressure to drive patient ventilators and other respiratory equipment, and that the delivered air is free of contaminants. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel noted that standards for air compressors have been developed by the Compressed Gas Association (CGA) and National Fire

Protection Association (NFPA) committes.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inadequate ventilation (breathing): Lack of adequate pressure may cause inadequate ventilation of the patient. (b) Inhalation of foreign substances: If the delivered air is not pure, the patient may inhale foreign substances such as bacteria and oil.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that portable air compressors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6250, to read as follows:

§ 868.6250 Portable air compressor.

(a) *Identification.* A portable air compressor is a device used to provide compressed air for medical use, e.g., to drive ventilators and other respiratory equipment.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33476 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N–1801]

Medical Devices; Classification of Gas Cylinders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas cylinders into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas cylinders:

1. Identification: A gas cylinder is a device used as a container for pressurized medical gas. This identification applies only to gas containers that are empty, i.e., to containers that are not filled with gas by the manufacturer or distributor. A cylinder is considered empty when the pressure level is one-tenth (1/10) of the labeled filling pressure at 21° C (70° F).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that a gas cylinder be classified into class II (performance standards) because the Panel believes that the design and materials used in the device must be controlled to assure that the cylinder is strong enough so that it does not rupture under use conditions. The Panel also believes that cylinders should be color coded according to the system accepted by most manufacturers in the United States (e.g., green for oxygen; gray for carbon dioxide; blue for nitrous oxide; orange for cyclopropane; red for ethylene; brown for helium; black for nitrogen; and yellow is for air) and should incorporate the pin-index safety system to reduce the possibility of delivering the wrong gas to the patient. In addition, the Panel believes that the cylinder should be clean and sterile to assure that the patient is protected from breathing contaminants that may cause airway infection and irritation. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel believes that the current Department of Transportation regulation for transport of medical gases in Title 49 of the Code of Federal Regulations provides an adequate and effective standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, gas cylinders.

5. Risks to health: (a) Trauma: If the cylinder is not strong enough it may rupture and cause injury to the patient and damage to other equipment, and may also endanger the patient's life due to lack of an inhaled gas source. (b) Infection and irritation of airway: Contaminants in the cylinder may result in infection or irritation of the patient's airway. (c) Wrong gas delivered to patient: Lack of the proper color code or a pin-index safety system may result in the wrong gas being delivered to the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas cylinders be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6275, to read as follows:

§ 868.6275 Gas cylinder.

(a) *Identification.* A gas cylinder is a device used as a container for pressurized medical gas. This identification applies only to gas containers that are empty, i.e., to containers that are not filled with gas by the manufacturer or distributor. A cylinder is considered empty when the pressure level is one-tenth (1/10) of the labeled filling pressure at 21° C (70° F).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33477 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N–1802]

Medical Devices; Classification of Gas Cylinder Holders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas cylinder holders into class II (performance standards).

FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas cylinder holders:

1. Identification: A gas cylinder holder is a device used to hold a gas cylinder in place.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas cylinder holders be classified into class II (performance standards) because the Panel believes that the design and materials used in the device must be controlled to assure adequate strength and stability to prevent damage caused by falling gas cylinders. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Damage and trauma: If the cylinder holder is not sufficiently strong or stable, the cylinder may fall and cause damage to equipment and injury to users.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas cylinder holders be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6285, to read as follows:

§ 868.6285 Gas cylinder holder.

(a) *Identification.* A gas cylinder holder is a device used to hold a gas cylinder in place.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments

may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33478 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1805]

Medical Devices; Classification of Calibration Gases

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying calibration gases into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of calibration gases:

1. Identification: A calibration gas is a device consisting of a container of gas of known concentration used to calibrate gas concentration measurement devices.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas cylinder holders be classified into class II (performance standards) because the Panel believes that the design and materials used in the device must be controlled to assure adequate strength and stability to prevent damage caused by falling gas cylinders. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Inappropriate therapy: Inaccurate gas concentration data may result in the incorrect calibration of concentration measurement devices, thereby causing inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that calibration gases be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6400, to read as follows:

§ 868.6400 Calibration gas.

(a) *Identification.* A calibration gas is a device consisting of a container of gas of known concentration used to calibrate gas concentration measurement devices.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33479 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1806]

Medical Devices; Classification of Anesthesia Stools

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthesia stools into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthesia stools:

1. Identification: An anesthesia stool is a device used as a stool for the anesthesiologist in the operating room.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that anesthesia stools be classified into class II (performance standards) because the Panel believes that the design and materials used in the device must be controlled to assure good electrical conductivity from the anesthesiologist to the floor to prevent explosion hazards from build-up of static electrical charges and to assure that the stool is stable at all seat heights. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted the development of a conductivity standard by the National Fire Protection Association.

4. Summary of data on which the recommendation is based: The Panel based it recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Burns, related injuries: Poor electrical conductivity from the operator to the floor may lead to an explosion due to a build-up of static electrical charges in the presence of flammable gas, causing burns and related injuries to nearby personnel. (b) Trauma: If the stool is unstable, the user may fall and be injured.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that anesthesia stools be classified into class I (general controls) with no exemptions. Because users are familiar with these simple devices and have used them successfully for many years without significant problems, the agency believes that a performance standard is unnecessary. The agency believes that general controls, including appropriate labeling regarding the conductivity or nonconductivity of the device and warnings against use of the nonconductive device in the presence of flammable anesthetic agents, are sufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6700, to read as follows:

§ 868.6700 Anesthesia stool.

(a) *Identification.* An anesthesia stool is a device used as a stool for the anesthesiologist in the operating room.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33480 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1810]

Medical Devices; Classification of Tracheobronchial Suction Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tracheobronchial suction catheters into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments. FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Adminstration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tracheobronchial suction catheters:

1. Identification: A tracheobronchial suction catheter is a device used to aspirate liquids or semisolids from a patient's upper airway.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that tracheobronchial suction catheters be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Trauma: Poor design (e.g., improper size, shape, or excessive rigidity) of the device may cause trauma to the patient's airway tissues. (b) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the tracheobronchial suction catheters be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6810, to read as follows:

§ 868.6810 Tracheobronchial suction catheter.

(a) *Identification.* A tracheobronchial suction catheter is a device used to aspirate liquids or semisolids from a patient's upper airway.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before (January 2, 1980,) submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33481 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1807]

Medical Devices; Classification of Patient Position Supports

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying patient position supports into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of patient position supports:

1. Identification: A patient position support is a device used to maintain the position of an anesthetized patient during surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that patient position supports be classified into class II (performance standards) because the Panel believes that the design and materials used in the device must be controlled to assure proper padding and positioning of supports to prevent soft tissue, joint, and peripheral nerve injury in unconscious, anesthetized patients; and to assure conductivity of electricity from the patient to the floor to prevent explosion hazards from build-up of static electrical charges in the presence of flammable gases. The Panel noted that the literature contains many reports of nerve, soft tissue, and joint injury from improperly designed, padded, or placed positioning supports. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted the development of standards for conductivity by the National Fire Protection Association.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device and their knowledge of the relevant literature.

5. Risks to health: (a) Tissue injury: Improper padding and positioning of supports may cause soft tissue, joint, and peripheral nerve damage to unconscious, anesthetized patients. (b) Burns and related injuries: Poor conductivity of electricity from the patient to the floor may lead to burns and related injuries from explosions caused by build-up of static electrical charges in the presence of a flammable gas.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that patient position supports be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6820, to read as follows:

§ 868.6820 Patient position support.

(a) *Identification.* A patient position support is a device used to maintain the position of an anesthetized patient during surgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers

Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33482 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1808]

Medical Devices; Classification of Medical Gas Yoke Assemblies

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying medical gas yoke assemblies into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of medical gas yoke assemblies:

1. Identification: A medical gas yoke assembly is a device used to connect medical gas cylinders to regulators and/or needle valves to supply gases for anesthesia or respiratory therapy. The device may include a gas filter.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that medical gas yoke assemblies be classified into class II (performance standards) because the Panel believes that the design, materials, and construction of the device must be controlled to assure that a proper connection is made between the gas cylinder and other devices to prevent fire and burns due to leakage of flammable gases. In addition, the Panel believes that the device should incorporate a system, such as a pin-index safety system, to prevent delivery of an inappropriate gas to the patient, and that the yoke filter should operate effectively to prevent contamination of the breathing system or infection of the patient. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted the development of standards for this device by the committees of the Compressed Gas Association, Inc., the British Standards Institute, and the Norges Standardiseringsforbund.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Burns and related injuries: Leakage of flammable gases due to poor connections may cause burns or related injuries to users. (b) Inappropriate therapy: Lack of a pin-index safety system may result in the delivery of an inappropriate gas to the patient. (c) Contamination or infection: An ineffective yoke filter may result in contamination of the breathing system or infection of the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that medical gas yoke assemblies be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6985, to read as follows:

§ 868.6985 Medical gas yoke assembly.

(a) *Identification.* A medical gas yoke assembly is a device used to connect medical gas cylinders to regulators and/or needle valves to supply gases for anesthesia or respiratory therapy. The device may include a gas filter.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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